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UNITED STATES DISTRICT COURT

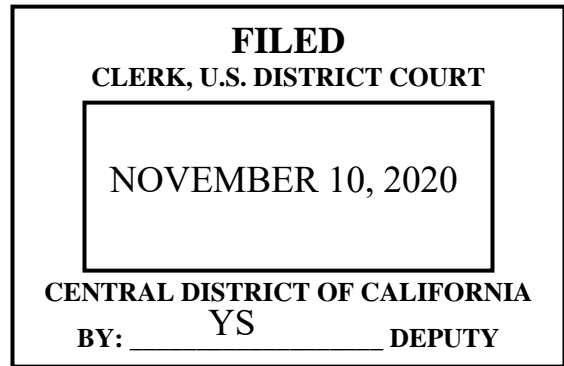
CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION

INTERNATIONAL MEDICAL
DEVICES, INC., a corporation
organized under the laws of California;
MENOVA INTERNATIONAL, INC., a
corporation organized under the laws of
California; and JAMES ELIST, MD, an
individual,

Plaintiffs,

v.

ROBERT CORNELL, MD, an
individual; AUGMENTA, LLC, a
corporation organized under the laws of
Delaware; AM FOUNDERS LLC, a
limited liability company organized
under the laws of Delaware;
AUGMENTA INVESTORS LLC, a
limited liability company organized
under the laws of Delaware; OAM



Case No. No. 2:20-cv-03503-CBM
(RAOx)

**FIRST AMENDED CIVIL
COMPLAINT FOR:**

1. **DEFEND TRADE SECRETS
ACT, 18 U.S.C. §§ 1836, et seq.**
2. **CALIFORNIA UNIFORM
TRADE SECRETS ACT, Cal.
Civ. Code § 3426.1;**
3. **CIVIL RICO, 18 U.S.C. § 1962(c);**
4. **CIVIL RICO, 18 U.S.C. §
1962(d);**
5. **TRADEMARK
INFRINGEMENT;**
6. **COUNTERFEIT MARK;**
7. **COPYRIGHT
INFRINGEMENT;**
8. **BREACH OF CONTRACT
(ROBERT CORNELL, MD);**
9. **BREACH OF CONTRACT
(RUN WANG, MD);**
10. **BREACH OF GOOD FAITH**



1 LLC, a limited liability company
 2 organized under the laws of Delaware;
 3 ROBERT J. CORNELL, M.D., P.A., a
 4 professional association organized
 5 under the laws of Texas; CORNELL
 6 COSMETIC UROLOGY, LLC, a
 7 limited liability company organized
 8 under the laws of Delaware; DAVID
 9 LOUIS NICHOLS, an individual;
 10 HUCK MEDICAL TECHNOLOGIES,
 11 INC., a corporation organized under the
 12 laws of Texas; HANS MISCHÉ, an
 13 individual; HANS MISCHÉ, LLC, a
 14 limited liability company organized
 15 under the laws of Minnesota;
 16 JONATHAN CLAVELL
 17 HERNANDEZ, MD, an individual;
 18 CLAVELL UROLOGY, PLLC, a
 19 professional limited liability corporation
 20 organized under the laws of Texas;
 21 RUN WANG, MD, an individual; RW
 22 GLOBAL MEN'S HEALTH
 23 CONSULTATION SERVICES, PLLC,
 24 a professional limited liability
 25 corporation organized under the laws of
 26 Texas; CAPITAL UROLOGY
 27 ASSOCIATES, LLC, a limited liability
 28 company organized under the laws of
 Delaware, RICHARD B. FINGER, an
 individual; LATA LIGNUM LLC, a
 limited liability company organized
 under the laws of Texas; and DOES 1
 through 10, inclusive,

Defendants.

**AND FAIR DEALING;
 11.UNFAIR COMPETITION;
 12.DECLARATORY RELIEF;
 and
 13.FALSE ADVERTISING, 15
U.S.C. § 1125(a)**

[DEMAND FOR JURY TRIAL]

INTRODUCTION

1
2 1. In January 2018, Defendant Dr. Robert Cornell contacted Plaintiff Dr.
3 James Elist through others about a cosmetic penile enhancement implant Dr. Elist had
4 developed over his lengthy career—the Penuma™ implant (“Penuma” or the
5 “Implant”). Dr. Elist and affiliated companies hold nine patents related to Penuma,
6 the only such male enhancement implant to receive clearance for commercial use by
7 the U.S. Food and Drug Administration (“FDA”) to date. Although much of the
8 intellectual property underlying Penuma is articulated in the patent portfolio,
9 Plaintiffs Dr. Elist, International Medical Devices, Inc. (“IMD”), and Menova
10 International, Inc. (“Menova”) (collectively, “Plaintiffs”) have also developed and
11 possess numerous trade secrets related to the use, functionality, and further
12 development of Penuma. For this reason, Penuma’s sole contract manufacturer has
13 been—at all times during its involvement with Penuma—subject to a strict
14 confidentiality agreement. Any doctor desiring Penuma training must first sign a non-
15 disclosure agreement.

16 2. In reality, Dr. Cornell’s stated interest in Penuma training was a ruse.
17 Dr. Cornell’s true intention was to gather confidential trade secrets and other
18 information with which he, along with his co-defendants, intended to (and eventually
19 did) launch a competing product. Unaware of Dr. Cornell’s plans, Dr. Elist hosted Dr.
20 Cornell for Penuma training on March 30, 2018. During that all-day training, Dr.
21 Cornell witnessed multiple Penuma procedures, asking Dr. Elist and his associates
22 numerous questions about the development and future of Penuma. Dr. Elist answered
23 those questions. During his visit, Dr. Cornell signed the non-disclosure agreement
24 with IMD (the “Penuma NDA”).

25 3. Following his Penuma training, Dr. Cornell used the information Dr.
26 Elist and his associates had provided – all subject to the Penuma NDA – to develop a
27 competing implant, now named Augmenta. Prior to “inventing” Augmenta, Dr.
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1 Cornell had never before developed a medical device nor filed or been granted a
2 patent. Armed with IMD's trade secrets, Dr. Cornell was able to do these things.
3 Using IMD's trade secrets and other confidential information, Dr. Cornell and others,
4 including Hans Mische and David Nichols, obtained a patent from the U.S. Patent and
5 Trademark Office ("USPTO") (U.S. Patent No. 10,413,413 B1 [the "'413 Patent'"])).
6 Those individuals also submitted another patent application that remains pending
7 using the same trade secrets and confidential information Dr. Cornell obtained from
8 IMD (U.S. Patent Application No. 16/238,821 [the "'821 Application'"])). In addition
9 to basing the entire application on Plaintiffs' trade secrets, Dr. Cornell, Mische and
10 Nichols also coopted Plaintiffs' copyrighted imagery in their patent filing. Of course,
11 Dr. Cornell, Mische and Nichols wrongfully claim inventorship. But they did not
12 invent; they stole. Dr. Cornell also included in his patent application Penuma
13 drawings he neither created nor had any right or authorization to use. The '413 Patent
14 is comprised entirely of *Plaintiffs'* intellectual property. The patent is thus the product
15 of fraud on the USPTO and is unenforceable. The '821 Application is likewise
16 comprised entirely of *Plaintiffs'* intellectual property, the product of fraud on the
17 USPTO, and should not be enforceable if granted.

18 4. Dr. Cornell received further help from defendant Dr. Run Wang, a
19 former member of Penuma's advisory board who breached the strict confidentiality
20 agreement he entered with IMD by providing substantial assistance and advice to Dr.
21 Cornell and the other co-defendants in exchange for an equity stake in the competing
22 Augmenta implant. Dr. Cornell has admitted under oath that Dr. Wang assisted with
23 the design and development of Augmenta – all of this occurred without Plaintiffs'
24 knowledge or consent and while Dr. Wang served on the Penuma advisory board.

25 5. Dr. Cornell's associate, Defendant Dr. Jonathan Clavell Hernandez, also
26 visited Dr. Wang's operating room in October 2019 with Dr. Wang's permission, on
27 information and belief, to watch a Penuma implant procedure and to obtain more of
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1 Plaintiffs' confidential information, including trade secrets, from Dr. Wang. Dr.
2 Clavell used the opportunity to closely observe the product packaging and implant.

3 6. Drs. Cornell and Clavell also purported to offer the Penuma implant to
4 prospective patients. For example, Dr. Cornell's website promoted him as a "Penuma
5 Penile Enhancement Specialist." A true and correct copy of a printout of Dr. Cornell's
6 website is attached as Exhibit D. Dr. Cornell further asserted on his website that
7 "using medically cleared silicone implants, Dr. Cornell has helped change the lives of
8 many men after just one simple in-office procedure." Exhibit D. In fact, Dr. Cornell
9 has never conducted any procedures using "medically cleared silicone implants" nor
10 is the procedure an "in-office procedure." Similarly, Dr. Clavell's website claimed
11 that he performed a ventral phalloplasty procedure that could be "made in conjunction
12 with penile implant surgery, penis enlargement procedures, such as Penuma, or can
13 be performed on its own." A true and correct copy of a printout of Dr. Clavell's
14 website is attached as Exhibit J. But Plaintiffs—the owners of Penuma—have never
15 authorized either Dr. Cornell or Dr. Clavell to offer, obtain or use the Penuma implant.
16 In fact, Plaintiffs sent Dr. Cornell a cease and desist letter on June 25, 2018,
17 demanding Dr. Cornell remove all Penuma-related content from his website. Dr.
18 Cornell did not do so. On August 4, 2019, Plaintiffs sent a second cease and desist
19 letter after receiving confused inquiries from potential patients about Dr. Cornell
20 offering Penuma. Plaintiffs demanded that Dr. Cornell remove false and misleading
21 information on his website about Penuma. Despite these demands, Dr. Cornell
22 continued to include references to Penuma on his website, advertise himself on
23 Google as a Penuma physician, use Penuma in Google ad campaigns, which he used
24 to confuse patients and ultimately divert them to his competing product. Defendants
25 eventually removed Penuma references from their websites and instead began to offer
26 Augmenta, representing that Augmenta was "safe and effective." This representation
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1 was also illegal, as Defendants offered their medical device absent the required FDA
2 clearance or approval.

3 7. Plaintiffs bring this action to stop the Defendants¹ from commercializing
4 Plaintiffs' trade secrets and other intellectual property and to redress the harm already
5 caused by the Defendants' acts of misappropriation, infringement, breach of contract,
6 and unfair competition.

7 8. Defendants' actions have significantly harmed Plaintiffs. Not only have
8 Defendants misappropriated certain of Plaintiffs' trade secrets and inserted them into
9 the public domain, the Defendants have misled the USPTO and have now started to
10 confuse the market with the aim of diverting customers interested in Penuma to Drs.
11 Cornell and Clavell, who then attempt to sell these customers the Defendants' product
12 – the Augmenta implant, an implant based entirely on intellectual property stolen from
13 Plaintiffs. Defendants' unlawful conduct continues to irreparably harm Plaintiffs.

14 9. For these reasons, Plaintiffs respectfully request that this Court find
15 Plaintiffs are entitled to monetary and injunctive relief. Based on Defendants' brazen,
16 surreptitious conduct, punitive damages are also warranted.

17 **General Background and Nature of the Action**

18 10. This Complaint arises out of Defendants' working together as an
19 enterprise under the Racketeer Influences and Corrupt Organization Act, 18 U.S.C.
20 §§ 1961 et seq. ("RICO") to misappropriate and use Plaintiffs' confidential
21 information, including its trade secrets and intellectual property, for their own benefit,
22 thereby violating the Defend Trade Secrets Act, RICO, and the California Uniform
23 Trade Secrets Act.

24 11. Defendants, by and through their wrongful conduct, willfully and with
25 actual knowledge, agreed to and did participate in the conduct of the enterprise affairs
26 through a pattern of racketeering activity for the purposes of intentionally depriving

27 _____
28 ¹ "Defendants" herein refers to all named defendants in this action.

1 Plaintiffs of their trade secrets, including confidential information and intellectual
2 property.

3 12. Violations of RICO predicate acts (*e.g.* theft of trade secrets in violation
4 of the Defend Trade Secrets Act) are how Defendants regularly conducted business
5 with Plaintiffs such that they are liable for harm done to Plaintiffs by their acts of
6 racketeering under RICO.

7 13. The detailed, non-exclusive list of acts of racketeering set forth in this
8 Complaint evidences a pattern of racketeering, the acts of which are related, not
9 isolated, and continue to date through both Defendants' continuing access to
10 Plaintiffs' trade secrets, including confidential information and intellectual property,
11 and the continuing use of such protected information by Defendants.

12 14. Since 2018, Defendants' continuing violations of the Defend Trade
13 Secrets Act, RICO, and the California Uniform Trade Secrets Act, through
14 Defendants continuing access to, and use of stolen and misappropriated trade secrets,
15 including confidential information and intellectual property, continue to injure
16 Plaintiffs.

17 15. All Defendants, by and through their continuing wrongful conduct,
18 willfully and with actual knowledge, agreed to and did conduct and participate in the
19 conduct of the enterprise affairs through a pattern of racketeering activity for the
20 purposes of intentionally depriving Plaintiffs of their trade secrets, including
21 confidential information and intellectual property.

22 16. Plaintiffs are pioneers in the aesthetic and reconstructive urology
23 industry. Plaintiff Dr. Elist is a renowned urologist and the holder of multiple patents
24 on subcutaneous silicone penile implants designed to expand the size of a penis by
25 facilitating tissue expansion. These patents protect Dr. Elist's invention: Penuma, the
26 first, and on information and belief, only penile implant for cosmetic correction
27 cleared by the FDA.
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1 17. Dr. Elist exerted immeasurable effort to clear Penuma for surgical use
2 with the FDA, including facilitating and paying for a five-year study on over 400
3 patients, the overwhelmingly successful results of which were published in a peer-
4 reviewed academic journal.

5 18. To protect the reputation and goodwill associated with Dr. Elist and
6 Penuma, Plaintiffs have taken care to ensure that Penuma is implanted solely by well-
7 trained and talented surgeons in the field of aesthetic and reconstructive urology. For
8 example, Dr. Elist personally trains any surgeon who wishes to offer the Implant to
9 patients. Because Dr. Elist desired to protect the trade secrets and intellectual property
10 related to the Penuma, not only is Penuma's sole contract manufacturer subject to a
11 strict confidentiality agreement, but all surgeons are required to sign confidentiality
12 agreements prior to any training and/or authorization to purchase and offer Penuma.
13 IMD also contracts with individual surgeons in the field of aesthetic and
14 reconstructive urology to sit on Penuma's advisory board for the purpose of
15 developing Penuma, educating surgeons in the field of aesthetic and reconstructive
16 urology, and addressing any challenges that arise in patients who have received the
17 Penuma implant. All Penuma advisory board members must sign strict confidentiality
18 agreements. Until August 2020, Dr. Wang was on Penuma's advisory board. Dr.
19 Wang has been subject to a confidentiality agreement with IMD since October 25,
20 2017.

21 19. In January 2018, Dr. Cornell contacted Gesiva Medical, LLC ("Gesiva"),
22 Penuma's United States distributor, regarding training to use the Penuma implant. Dr.
23 Cornell had no prior experience with cosmetic penile implants before he reached out
24 to Gesiva to learn about Penuma.

25 20. In response to Dr. Cornell's inquiries, Dr. Elist agreed to provide training
26 to Dr. Cornell on Penuma in Beverly Hills, California. The training took place on
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1 March 30, 2018. During his visit, Dr. Cornell signed the Penuma NDA and patient
2 waiver forms to observe four Penuma implant procedures.

3 21. Unlike other training sessions, however, Dr. Cornell's interest in Penuma
4 went beyond excitement for the revolutionary product or the surgical technique to
5 include the research and development pipeline plans for future iterations of the
6 Penuma implant. Dr. Cornell asked Dr. Elist direct questions about Penuma research
7 and development plans. Dr. Cornell took copious notes during the visit. Dr. Cornell
8 asked about various physical characteristics of the implant and about plans to modify
9 those attributes. Relying on the NDA and the natural assumption that Dr. Cornell was
10 genuinely interested in purchasing and utilizing Penuma implants in his surgical
11 practice, Dr. Elist shared with Dr. Cornell the requested future plans to update the
12 product design of Penuma and the surgical technique associated with the placement
13 of the Penuma implant. Dr. Elist would not have provided Dr. Cornell with training
14 on Penuma and would not have disclosed or discussed any Penuma research and
15 development plans with Dr. Cornell absent the Penuma NDA. In fact, Dr. Elist does
16 not generally discuss any Penuma research and development plans with prospective
17 Penuma surgeons. Such discussions are generally reserved for Penuma's advisory
18 board members, such as Dr. Wang. The nature of Dr. Cornell's visit demonstrated
19 the expectation of confidentiality and imposed a duty on Dr. Cornell not to divulge or
20 exploit the confidential information he received.

21 22. Within days of returning to Texas, in early April 2018, Dr. Cornell and
22 Hans Mische began working on a provisional patent application for a cosmetic penile
23 implant based entirely on what Dr. Cornell learned about Penuma from Plaintiffs.
24 This effort was funded, in part, on information and belief, by Richard Finger and Lata
25 Lignum LLP, a limited liability partnership controlled by Finger, an investor who
26 advised and encouraged Dr. Cornell's deceitful and illegal conduct.

23. In violation of the NDA, Dr. Cornell shared confidential information obtained from Plaintiffs, including with Mische, Finger, and others. Mische was entirely aware that Dr. Cornell was subject to an NDA, because Dr. Cornell sent Mische a copy of the NDA as he was also sending him the confidential information of Plaintiffs in violation of the NDA. Mische offered his opinion that the NDA did not present any issues. On information and belief, Mische established Hans Mische LLC to receive funds related to developing the Augmenta implant from Plaintiffs' stolen trade secrets.

24. Dr. Cornell's visit to California was nothing more than a ruse to steal trade secrets Dr. Elist has spent a lifetime creating, a ruse that was orchestrated, on information and belief, in concert with Mische, Finger, and others. In addition to working on a provisional patent application to cement their theft of Plaintiffs' intellectual property and trade secrets, Dr. Cornell, Finger, Mische, and others also established Augmenta LLC, OAM LLC, Augmenta Investors LLC, and AM Founders LLC to commercialize and profit from that theft.

25. On July 23, 2018, Dr. Cornell and Mische filed their first provisional application for a cosmetic penile implant based entirely on trade secrets Dr. Cornell learned about Penuma from Dr. Elist, namely that Dr. Elist was considering the inclusion of one or more mesh tabs, the employment of absorbable sutures, and the use of an antibacterial agent in future iterations of Penuma. On December 14, 2018, Dr. Cornell and Mische filed another provisional application for a cosmetic penile implant, also based entirely on what Dr. Cornell learned about Penuma from Dr. Elist.

26. At some point in the latter half of 2018, Dr. Cornell and Mische ceased working together and Dr. Cornell brought in Huck Medical Technologies, Inc. ("Huck Medical") and Nichols to continue developing and commercializing Dr. Elist's intellectual property and trade secrets.

1 27. Also, in the latter half of 2018, Drs. Cornell and Clavell began consulting
2 with Dr. Wang, a member of Penuma's advisory board, regarding development and
3 commercialization of Augmenta. Dr. Clavell had previously worked with Dr. Wang
4 before he joined Dr. Cornell's practice.

5 28. As a member of Penuma's advisory board, Dr. Wang had access to, and
6 intimate knowledge of, Plaintiffs' trade secrets. Since October 25, 2017, Dr. Wang
7 has been subject to a strict confidentiality clause as part of his advisory board
8 consulting agreement with IMD ("Consulting Services Agreement"). A true and
9 correct copy is attached as Exhibit M. As part of that Consulting Services Agreement,
10 he also agreed not to assist or consult with any third parties regarding the development
11 of silicone block penile implants. On June 8, 2018, IMD and Dr. Wang signed an
12 amendment to the Consulting Services Agreement through which Dr. Wang agreed
13 to assist IMD with further study of the Penuma.

14 29. In flagrant violation of his agreement with IMD, Dr. Wang began
15 providing extensive advice, assistance and feedback to Dr. Cornell, Dr. Clavell, and
16 Huck Medical regarding the development of the Augmenta implant. In December
17 2018, Dr. Wang conducted a cadaver study with the Augmenta implant. On
18 information and belief, Dr. Wang used Penuma confidential and trade secret
19 information for Defendants' benefit in violation of his contractual obligations to IMD.
20 In exchange for his assistance, Dr. Wang was given an ownership interest in
21 Augmenta LLC via his professional limited liability company, RW Global Men's
22 Health Consultation Services. Dr. Clavell also maintains an ownership interest in
23 Augmenta, LLC through Capital Urology Associates LLC. On information and
24 belief, Dr. Wang also worked to facilitate distribution agreements for Augmenta in
25 China. In October 2019, Dr. Wang invited Dr. Clavell to his operating room to
26 observe a Penuma procedure and further discuss confidential Penuma information,
27 including Penuma trade secrets. Overall, Dr. Wang's support of Defendants has been
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1 so extensive that he was listed on Augmenta's website in 2020 not only as an
2 Augmenta physician, but as Chief Executive Officer (CEO) of Augmenta, LLC.
3 When Dr. Wang was asked by Plaintiffs about why he was listed as the Augmenta,
4 LLC CEO on Augmenta's website, Dr. Wang denied any involvement with
5 Augmenta, LLC (outside of an academic study) and feared he may lose his positions
6 at major academic institutions if there was even the appearance that he had an
7 executive role with or investment in a medical device company.

8 30. On January 3, 2019, Dr. Cornell formally filed two non-provisional
9 patent applications with the USPTO based on the provisional applications with Dr.
10 Cornell, Mische, and Nichols each listed as a co-inventor.

11 31. The first patent application, U.S. Patent Application No. 16/238,792,
12 matured into U.S. Patent No. 10,413,413 (the "'413 Patent") on September 17, 2019.
13 The second application, U.S. Patent Application No. 16/238,821 (the "'821
14 Application"), is pending and has been recently published on January 23, 2020, as
15 U.S. Pub. No. 2020/0022812 A1. Plaintiffs did not learn about these nefarious actions
16 until after the '413 Patent had been issued by the USPTO on September 17, 2019. On
17 information and belief, the patent application for the '413 Patent was never published,
18 making it impossible for Plaintiffs to discover the Defendants' misconduct before the
19 USPTO.

20 32. In their patent applications for the '413 Patent and '821 Application, a
21 copyrighted image from a video authored by Dr. Elist and available on his website
22 was utilized. Of course, this use was not authorized; it was copyright infringement.
23 Defendants willfully used the image from Dr. Elist's video, fully aware of its origin.

24 33. During the prosecution of the patent application of the '413 Patent, the
25 USPTO rejected all claims citing Dr. Elist's U.S. Patent No. 6,537,204 (the "'204
26 Patent") and U.S. Patent No. 8,986,193 (the "'193 Patent") as prior art. In other
27 words, all claims in the Defendants' patent application for the '413 Patent were
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1 considered not patentable over Dr. Elist's patent. Defendants presented nothing novel
2 or inventive in their patent application.

3 34. To overcome the USPTO's rejection and present inventive subject
4 matter, Defendants relied on Plaintiffs' misappropriated trade secrets. Defendants,
5 without any authorization and in breach of Dr. Cornell's contractual obligations,
6 highlighted a future change of Penuma that was disclosed to Dr. Cornell on March
7 30, 2018, during his visit to Dr. Elist's clinic—namely that the penile implant would
8 contain internal pockets or voids of space. Dr. Elist's decision to include internal
9 pockets or voids of space in future iterations of Penuma was based solely on his
10 clinical observation of patients' experiences with Penuma—observations Dr. Cornell
11 could not have made himself given that he had no experience with cosmetic penile
12 implants prior to his exposure to Penuma.

13 35. Defendants further provided these trade secrets, which were stolen from
14 Plaintiffs, in an interview with the patent examiner on April 25, 2019. In doing so,
15 Defendants succeeded in convincing the examiner that Plaintiffs' trade secrets—
16 which the Defendants had misappropriated and claimed as their own—are indeed the
17 inventive subject matter of the '413 Patent. Defendants then incorporated the
18 misappropriated trade secrets in amendments to their patent claims, filed April 30,
19 2019. Based on these trade secrets, Defendants improperly obtained the '413 Patent,
20 a patent that publicly disclosed trade secrets Plaintiffs reasonably sought to, and
21 previously did, protect. Of course, Dr. Elist is not included as an inventor on the '413
22 Patent, although the patent is the result of Dr. Elist's intellectual property. Dr. Elist
23 should be listed as the sole inventor of the '413 Patent, which should be unenforceable
24 as issued.

25 36. Defendants also incorporated additional trade secrets stolen from
26 Plaintiffs in the '413 Patent, including the inclusion of one or more mesh tabs, the
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1 employment of absorbable sutures, and the use of an antibacterial agent in future
2 iterations of Penuma.

3 37. Defendants' pending '821 Application is also based on Plaintiffs' trade
4 secrets. Without the misappropriated trade secrets, the '821 Application contains zero
5 inventive material. The '821 Application should be voided.

6 38. Contemporaneously with the above actions, and from on or between at
7 least April 2018 through April 15, 2020, Dr. Cornell advertised on his website and
8 through targeted Internet advertising schemes his connections to Penuma, claiming to
9 perform the Penuma procedure even though he had not completed his training and,
10 therefore, could not purchase Penuma implants from IMD, the only distributor. These
11 advertisements also contained misleading information about the results of the Penuma
12 implant procedure and the recovery period. These advertisements infringed on
13 Penuma's federally registered trademark name (the "Penuma Mark").

14 39. Similarly, Dr. Clavell advertised the Penuma Mark on his website until
15 at least April 25, 2020. Much like Dr. Cornell's advertisements, on information and
16 belief, Dr. Clavell's statement was designed to confuse potential patients visiting the
17 his website to think they can get a Penuma implant in conjunction with a ventral or
18 cosmetic phalloplasty procedure performed by Dr. Clavell, despite the fact that Dr.
19 Clavell did not, and has never, had permission to use the Penuma Trademark on his
20 website, and has never been authorized to implant Penuma.

21 40. The aim of the advertisements of Drs. Cornell and Clavell was to create
22 confusion in the relevant market, all with the aim of redirecting potential customers
23 of Plaintiffs to the Defendants to increase future sales of Augmenta and fees charged
24 by the Defendants for their surgical procedures. Dr. Elist's office received no fewer
25 than 23 separate calls and messages from potential patients confused about whether
26 Dr. Cornell is offering the Penuma implant and procedure and whether the Penuma
27 and Augmenta implants are related or synonymous. Dr. Cornell persisted in these
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1 targeted Internet advertising schemes even after repeated requests by Plaintiffs that
2 he cease and desist such behavior and brazenly, even after being served the complaint
3 in this action.

4 41. On information and belief, Dr. Cornell personally met with patients
5 wanting to receive Penuma implants and instead, attempted to redirect them to an
6 Augmenta implant despite the fact that Augmenta implants were not yet FDA-cleared
7 or approved. During these consultations, Dr. Cornell provided negative feedback
8 regarding Penuma to patients despite never having performed a single Penuma
9 implant procedure. On information and belief, Dr. Cornell's intention was to
10 convince these patients to use Augmenta in place of Penuma. These consultations by
11 Dr. Cornell with potential Penuma patients continued well into 2020, according to Dr.
12 Cornell.

13 42. On information and belief, Defendants are now taking steps to
14 commercialize stolen trade secrets by selling Augmenta to the medical community at
15 large, despite the fact that the Defendants have not obtained any FDA clearance or
16 approval on their product. Defendants promoted the Augmenta implant through a
17 publicly available website both before and well after this action was initiated in April
18 2020. Given the market confusion the Defendants have created through their
19 advertising schemes, this wrongful conduct further damages Plaintiffs.

20 43. Plaintiffs seek this Court's assistance to stop Defendants from continuing
21 their illegal and injurious conduct. Plaintiffs have suffered and will continue to suffer
22 irreparable harm unless Defendants are enjoined from further abuse of Plaintiffs' trade
23 secrets and intellectual property, including withdrawal of any pending regulatory
24 submission with FDA. Plaintiffs seek an order for impoundment and destruction of
25 all infringing copies of its content and corrective advertising to remedy the
26 Defendants' unfair competition. Plaintiffs also seek declaratory relief from the
27 Defendants and damages from the Defendants for their wrongful conduct, including
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1 but not limited to invalidation of the '413 Patent, voiding the pending '821
2 Application, compensatory damages, statutory damages, treble damages, and punitive
3 damages, as well as an award of Plaintiffs' costs and reasonable attorneys' fees
4 incurred in this action.

5 **PARTIES**

6 44. IMD is a corporation organized under the laws of California, with its
7 principal place of business at 8500 Wilshire Boulevard, Suite 707, Beverly Hills,
8 California 90211. IMD was created to serve as the distribution entity for Penuma to
9 surgeons. IMD is also the registered entity for Penuma with the FDA.

10 45. Menova is a corporation organized under the laws of California, with its
11 principal place of business at 8500 Wilshire Boulevard, Suite 707, Beverly Hills,
12 California 90211. Menova was created to hold the intellectual property associated
13 with Penuma. Menova holds the Penuma Mark and all international intellectual
14 property rights.

15 46. Dr. Elist is an individual residing in Beverly Hills, California. Dr. Elist
16 is the inventor of U.S. Patent Nos. 5,445,594 (the "'594 Patent") (implant for
17 expanding penile girth and length); 5,669,870 (the "'870 Patent") (penile implant for
18 improved appearance); 5,899,849 (the "'849 Patent") (subcutaneous penile implant);
19 D462,770 (the "'770 Design Patent") (tapered penile implant); 6,475,137 (the "'137
20 Patent") (subcutaneous penile implant); 6,537,204 (the "'204 Patent") (structural
21 penile implant); 8,986,193 (the "'193 Patent") (penile implant); 9,504,573 (the "'573
22 Patent") (prosthesis for improved penis function); and 10,350,070 (the "'070 Patent")
23 (prosthesis for improved penis function).

24 47. Dr. Robert Cornell is an individual residing in Houston, Texas. On
25 information and belief, he is the founder of Augmenta, LLC, Cornell Cosmetic
26 Urology, LLC, and Capital Urology Associates, LLC; and he is the manager of
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1 Augmenta Investors LLC, AM Founders LLC, Cornell Cosmetic Urology LLC, and
2 Capital Urology Associates LLC.

3 48. On information and belief, Augmenta, LLC is a limited liability
4 company, organized under the laws of Delaware, with its principal place of business
5 at 1315 St. Joseph Parkway, Suite 1700, Houston, Texas 77002, the same address at
6 which Dr. Cornell operates his urology practice. On information and belief,
7 Augmenta, LLC was formed by Dr. Cornell to capitalize on the Plaintiffs' intellectual
8 property and trade secrets. Dr. Cornell is the manager of Augmenta, LLC. Augmenta,
9 LLC is a "person" within the meaning of 18 U.S.C. §§ 1961(3); 1962(c).

10 49. On information and belief, AM Founders LLC is a limited liability
11 company, organized under the laws of Delaware, with its principal place of business
12 at 1315 St. Joseph Parkway, Suite 1700, Houston, Texas 77002. On information and
13 belief, the members of AM Founders LLC are Cornell Cosmetic Urology, LLC,
14 Capital Urology Associates, LLC, and Lata Lignum, LLC; the purpose of AM
15 Founders LLC is to make equity investments into Augmenta Investors LLC, which in
16 turn, is to make equity investments into Augmenta, LLC. The manager of AM
17 Founders LLC is Dr. Cornell. AM Founders LLC is a "person" within the meaning
18 of 18 U.S.C. §§ 1961(3); 1962(c).

19 50. On information and belief, Augmenta Investors LLC is a limited liability
20 company, organized under the laws of Delaware, with its principal place of business
21 at 1315 St. Joseph Parkway, Suite 1700, Houston, Texas 77002. On information and
22 belief, AM Founders LLC is currently a 100 percent member of Augmenta Investors
23 LLC and the purpose of Augmenta Investors LLC is to make equity investments into
24 Augmenta LLC. The manager of Augmenta Investors LLC is Dr. Cornell. Augmenta
25 Investors LLC is a "person" within the meaning of 18 U.S.C. §§ 1961(3); 1962(c).

26 51. On information and belief, OAM LLC is a limited liability company,
27 organized under the laws of Delaware, with its principal place of business at 1315 St.
28

1 Joseph Parkway, Suite 1700, Houston, Texas 77002. On information and belief, Dr.
2 Cornell is a 60 percent member and Hans Mische is a 40 percent member of OAM
3 LLC and OAM LLC is a 5 percent member of Augmenta, LLC. OAM LLC is a
4 “person” within the meaning of 18 U.S.C. §§ 1961(3); 1962(c).

5 52. On information and belief, Robert J. Cornell, M.D., P.A (the “Cornell
6 PA”) is a professional association, organized under the laws of Texas, with its
7 principal place of business at 1315 St. Joseph Parkway, Suite 1700, Houston, Texas
8 77002. On information and belief, the Cornell PA is Dr. Cornell’s alter ego and/or
9 the entity through which he does business. The Cornell PA is a “person” within the
10 meaning of 18 U.S.C. §§ 1961(3); 1962(c).

11 53. On information and belief, Cornell Cosmetic Urology, LLC is a limited
12 liability company, organized under the laws of Delaware, with its principal place of
13 business at 1315 St. Joseph Parkway, Suite 1700, Houston, Texas 77002. Cornell
14 Cosmetic Urology, LLC, on information and belief, is owned and solely controlled
15 by Dr. Cornell and is the manager of Cornell Cosmetic Urology, LLC. Cornell
16 Cosmetic Urology, LLC is a “person” within the meaning of 18 U.S.C. §§ 1961(3);
17 1962(c).

18 54. On information and belief, David Louis Nichols is an individual residing
19 in Bullard, Texas. He is the Director of Huck Medical Technologies, Inc.

20 55. On information and belief, Huck Medical Technologies, Inc. is a
21 corporation, organized under the laws of Texas, with its principal place of business at
22 111 Cash Street, Jacksonville, Texas 75766. Huck Medical Technologies, Inc. is a
23 “person” within the meaning of 18 U.S.C. §§ 1961(3); 1962(c).

24 56. On information and belief, Hans Mische is an individual residing in Grey
25 Eagle, Minnesota. Mische is the registered agent and manager for Hans Mische, LLC.

26 57. On information and belief, Hans Mische, LLC is a limited liability
27 company, organized under the laws of Minnesota, with its principal place of business
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1 at 218 4th Avenue South #D6, St. Cloud, Minnesota 56301. On information and
2 belief, Hans Mische, LLC is currently inactive, having been administratively
3 terminated by the State of Minnesota Secretary of State. Hans Mische, LLC is a
4 “person” within the meaning of 18 U.S.C. §§ 1961(3); 1962(c).

5 58. On information and belief, Dr. Jonathan Clavell Hernandez is an
6 individual residing in Houston, Texas, and is the owner of Clavell Urology, PLLC
7 (the “Clavell PA”).

8 59. On information and belief, the Clavell PA is a professional limited
9 liability corporation, organized under the laws of Texas, with its principal place of
10 business at 1315 St. Joseph Parkway, Suite 1700, Houston, Texas 77002. On
11 information and belief, the Clavell PA is Dr. Clavell’s alter ego and/or the entity
12 through which he does business. The Clavell PA is a “person” within the meaning of
13 18 U.S.C. §§ 1961(3); 1962(c).

14 60. On information and belief, Dr. Run Wang is an individual residing in
15 Houston, Texas, and is the owner of RW Global Men’s Health Consultation Services,
16 PLLC. Up until August 2020, Dr. Wang was on the Penuma advisory board.

17 61. On information and belief, RW Global Men’s Health Consultation
18 Services, PLLC is a professional limited liability corporation, organized under the
19 laws of Texas, with its principal place of business at 4108 Amherst Street, Houston,
20 Texas 77005. On information and belief, RW Global Men’s Health Consultation
21 Services, PLLC is Dr. Wang’s alter ego and/or the entity through which he does
22 business. RW Global Men’s Health Consultation Services, PLLC is a “person”
23 within the meaning of 18 U.S.C. §§ 1961(3); 1962(c).

24 62. On information and belief, Capital Urology Associates LLC is a limited
25 liability company, organized under the laws of Delaware, with its principal place of
26 business at 1315 St. Joseph Parkway, Suite 1700, Houston, Texas 77002. Capital
27 Urology Associates LLC, on information and belief, is owned by a group of urologists
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1 who are investors in Augmenta, including Drs. Cornell, Clavell, and Wang. On
2 information and belief, Dr. Cornell is the Manager of Capital Urology Associates
3 LLC. Capital Urology Associates, LLC is a “person” within the meaning of 18 U.S.C.
4 §§ 1961(3); 1962(c).

5 63. On information and belief, Richard B. Finger is an individual residing in
6 Houston, Texas, and he is the owner of Lata Lignum LLC.

7 64. On information and belief, Lata Lignum LLC is a professional limited
8 liability corporation, organized under the laws of Texas, with its principal place of
9 business at 7 Pine Hill Lane, Houston, Texas 77019. On information and belief, Lata
10 Lignum LLC is solely owned by Richard B. Finger and is a 44 percent member of
11 AM Founders LLC. Lata Lignum, LLC is a “person” within the meaning of 18 U.S.C.
12 §§ 1961(3); 1962(c).

13 65. Plaintiffs are unaware of the true names and capacities, whether
14 individual, corporate, associate, or otherwise, of defendant DOES 1 through 10,
15 inclusive, or any of them, and therefore sues these defendants, and each of them, by
16 such fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint
17 when the status and identities of these defendants are ascertained.

18 66. Upon information and belief, at all times relevant, each of the Defendants
19 was the agent of the other Defendants, and in doing the things alleged, each defendant
20 was acting within the course and scope of its agency and was subject to and under the
21 supervision of its co-defendants. Plaintiffs are informed and believe that each of the
22 fictitiously named defendants is responsible in some manner for the injuries to
23 Plaintiffs alleged in this Complaint. Plaintiffs further allege that their injuries were
24 proximately caused by each and all such Defendants.

25 67. Defendants together constituted an association-in-fact, that is, an
26 “enterprise” within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c) and, at all
27 relevant times, were engaged in, and the activities of which affected, interstate and/or
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1 foreign commerce within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c). Through
2 the enterprise, Defendants took actions in concert with each other for the express
3 purpose of unlawfully obtaining possession of, and using Plaintiffs' trade secrets,
4 including confidential information and intellectual property.

5 68. At all times material to this action, each defendant was a co-conspirator
6 of and with each of the other Defendants, and the acts of each defendant was in the
7 scope of the relationship. In committing the acts and failing to act as set forth herein,
8 each defendant acted with the knowledge, permission, and the consent of each of the
9 other Defendants. Each defendant aided and abetted the other Defendants in the acts
10 or omissions alleged in this Complaint.

11 **JURISDICTION AND VENUE**

12 69. This Court has subject matter jurisdiction over the parties based on
13 principles of diversity, pursuant to 28 U.S.C. § 1332(a), as the action is between a
14 citizen and corporations of California and citizens of another state. Dr. Elist is a
15 citizen of California and Menova and IMD are both organized under the laws of
16 California, with their principal place of business in Beverly Hills, California. Dr.
17 Cornell, Dr. Clavell, Dr. Wang, Richard B. Finger, and David Nichols are citizens
18 and residents of Texas. Hans Mische is a citizen and resident of Minnesota. Hans
19 Mische LLC is incorporated under Minnesota law and is based in Minnesota.
20 Augmenta, LLC, AM Founders LLC, Augmenta Investors LLC, Capital Urology
21 Associates, LLC, Cornell Cosmetic Urology, LLC, and OAM LLC are incorporated
22 under Delaware law and based in Houston, Texas. The Cornell PA, the Clavell PA,
23 and RW Global Men's Health Consultation Services, PLLC are organized under the
24 laws of Texas and based in Houston, Texas. Huck Medical Technologies, Inc. and
25 Lata Lignum, LLC are incorporated under Texas law and based in Texas. The amount
26 in controversy exceeds \$75,000.

1 70. This Court also has subject matter jurisdiction under 18 U.S.C. § 1836
2 as well as 28 U.S.C. §§ 1331 and 1338(b), as this action includes violations of the
3 federal Defend Trade Secrets Act, 18 U.S.C. § 1836; the federal Copyright Act of
4 1976, 17 U.S.C. § 101, *et seq.*; Federal Trademark Law, 15 U.S.C. § 1114, *et seq.*; the
5 Racketeer Influences and Corrupt Organization Act, 18 U.S.C. §§ 1961 *et seq.*; and
6 related claims of unfair competition.

7 71. Additionally, this Court has supplemental jurisdiction under 28 U.S.C. §
8 1367.

9 72. This Court has personal jurisdiction over the Defendants for the
10 following reasons: (i) Dr. Cornell traveled to California to meet with Dr. Elist and that
11 is where the theft of Plaintiffs' trade secrets and intellectual property occurred; (ii)
12 Dr. Cornell signed the Penuma NDA in California, which provides that it "shall be
13 construed and enforced in accordance with the internal laws of the State of
14 California;" (iii) Dr. Wang entered the Consulting Services Agreement, which
15 provides that it "shall be construed and enforced in accordance with the substantive
16 laws of the State of California" and] "[a]ny action or proceeding arising under or
17 relating to this Agreement shall be brought only in the courts of the State of California,
18 County of Los Angeles, or if it has or can acquire jurisdiction, in the United States
19 District Court for the District of California;" (iv) the Defendants regularly do business
20 or solicit business, engage in other persistent courses of conduct, and/or derive
21 substantial revenue from products and/or services provided to individuals in
22 California; (v) the Defendants have purposefully established substantial, systematic,
23 and continuous contacts with California and expect or should reasonably expect to be
24 in court here; and (vi) the Defendants purposefully availed themselves of the privilege
25 of conducting activities within California and the causes of action alleged herein arise
26 out of the Defendants' contacts with California. Furthermore, Defendants are alleged
27 to be co-conspirators in a scheme to misappropriation Plaintiffs' trade secrets in
28

1 California, and the Court has personal jurisdiction over at least one of the co-
2 conspirators, therefore personal jurisdiction extend to all Defendants. 18. U.S.C. §
3 1965. Thus, this Court's exercise of jurisdiction over the Defendants will not offend
4 traditional notions of fair play and substantial justice.

5 73. Venue is proper in this Judicial District because a substantial part of the
6 events given rise to this Complaint occurred in this District, and the Defendants are
7 subject to personal jurisdiction in this District.

8 **FACTUAL ALLEGATIONS COMMON TO ALL COUNTS**

9 74. Penuma is the first, and on information and belief, only cosmetic
10 correction penile implant cleared by the FDA.

11 75. Dr. Elist is the sole inventor of the Penuma penile implant, which he
12 created after years of working in the field of aesthetic and reconstructive urology, and
13 specifically, with penile enhancement procedures.

14 76. Dr. Elist is the inventor of no fewer than nine patents on penile implants
15 dating back to August 29, 1995, which are more particularly described above. These
16 patents protect Dr. Elist's inventions, including Penuma—a subcutaneous silicone
17 penile implant designed to expand the size of a penis by facilitating tissue
18 expansion—the commercial product that embodies his inventions.

19 77. As with all innovative technologies, Plaintiffs also possessed trade
20 secrets related to their constant efforts to update Dr. Elist's invention. One method
21 by which Plaintiffs protected these trade secrets was by requiring a strict
22 confidentiality agreement with Penuma's sole contract manufacturer.

23 78. Additionally, to ensure that Penuma was implanted solely by well-
24 trained and talented surgeons in the field of aesthetic and reconstructive urology, Dr.
25 Elist personally met with, and trained, surgeons that wanted to purchase and implant
26 Penuma. Dr. Elist started these trainings in 2017 with all surgeons signing a non-
27 disclosure agreement with IMD at the time of such trainings.

1 79. The training program was initially very small and consisted only of
2 surgeons who also served on Penuma's advisory board. The surgeons who sat on
3 Penuma's advisory board, including Dr. Wang, were subject to strict confidentiality
4 agreements. Penuma's advisory board was created in part to develop the surgeon
5 training program, and to provide Plaintiffs assistance in developing strategies and
6 tactics to be used to educate future trained providers of the Penuma implant.

7 80. On October 25, 2017, Dr. Wang entered a Consulting Services
8 Agreement with IMD to participate as a member of Penuma's advisory board. All
9 members of Penuma's advisory board were required to enter this agreement. The
10 Consulting Services Agreement prohibited Dr. Wang from disclosing any confidential
11 information he received from Plaintiffs, including any material, information, data, and
12 devices developed in the course of performing his consulting services. Further, Dr.
13 Wang agreed to assign to IMD "any ideas, inventions, improvements, or suggestions
14 arising from [Dr. Wang's] performance of the Consulting Services, whether made
15 alone or in conjunction with others." Dr. Wang also agreed that if the confidential
16 information and trade secrets he gained access to pursuant to his Penuma advisory
17 board position "were disclosed to or for the benefit of any of [IMD's] competitors,"
18 IMD "would suffer immediate and irreparable harm." On June 8, 2018, Dr. Wang
19 and IMD agreed to an amended to the Consulting Service Agreement through which
20 Dr. Wang agreed to provide additional research for Penuma. A true and correct copy
21 of the Consulting Services Agreement and Amendment is attached as Exhibit M.

22 81. On January 11, 2018, after hearing of Penuma, Dr. Cornell emailed Tom
23 Hopper, the president of Gesiva, to request Penuma training. Gesiva is the exclusive
24 distributor of the Penuma implant in the United States. Dr. Cornell represented he
25 became aware of Gesiva and Penuma at a medical conference.

26 82. Mr. Hopper replied to Dr. Cornell and informed him that there was a
27 multi-step process to be approved to use the Penuma implant, including meeting with
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1 Dr. Elist in Beverly Hills, California, to observe multiple Penuma implant procedures
2 along with a Gesiva representative. Dr. Cornell advised on January 12, 2018, that he
3 saw “real opportunity to expand the level of service” he currently offered his patients
4 and wanted to learn more about Penuma “expeditiously.”

5 83. On January 22, 2018, Gesiva representative Duncan Louie met with Dr.
6 Cornell in person and confirmed Dr. Cornell’s interest in Penuma. Mr. Louie told Dr.
7 Cornell he would arrange for dates for Dr. Cornell to observe the Penuma procedure
8 at Dr. Elist’s Beverly Hills facility.

9 84. Dr. Cornell visited Dr. Elist’s clinic on March 30, 2018. This was the
10 first opportunity Dr. Cornell had to learn any detailed information about Penuma.

11 85. During Dr. Cornell’s visit to Dr. Elist’s clinic, Dr. Cornell signed the
12 March 30, 2018 Penuma NDA with IMD. Under the Penuma NDA, Dr. Cornell
13 agreed to “protect and hold in the strictest confidence the Confidential Information;
14 [] not disclose any Confidential Information to any person or entity, unless required
15 by law or other regulatory authority . . . and [] not use directly or indirectly the
16 Confidential Information for its own benefit or benefit of any other person.” The
17 definition of “Confidential Information” included, among other things, information
18 relating to “past, present, or future products, services, [] techniques or technical
19 information and data” regarding Penuma. The definition of Confidential Information
20 thus includes, but is not limited to, trade secrets and trade secret information. The
21 Penuma NDA is governed by California law and allows for the recovery of attorneys’
22 fees. A true and correct copy of the Penuma NDA is attached as Exhibit A. Dr.
23 Cornell was also presented with patient waiver forms with respect to the four Penuma
24 procedures he witnessed on March 30, 2018.

25 86. Dr. Cornell signed the Penuma NDA during his visit. He was granted
26 access to the Confidential Information, including, but not limited to, trade secrets and
27 trade secret information. Dr. Cornell knew much of the information disclosed to him
28

1 during his visit was confidential and proprietary. Dr. Elist answered Dr. Cornell's
2 questions because he believed this information would be used to lawfully incorporate
3 the use of Penuma into Dr. Cornell's practice. At the time, Dr. Elist was unaware of
4 Dr. Cornell's true motives, which were to use Plaintiffs' trade secrets and intellectual
5 property to start a competing venture, confuse consumers, trade on Plaintiffs'
6 goodwill, and benefit himself at the expense of Plaintiffs.

7 87. During his training with Dr. Elist, Dr. Cornell specifically asked about
8 the research and development plans for Penuma. Dr. Elist provided Dr. Cornell with
9 training on Penuma and responded to Dr. Cornell's questions with confidential and
10 trade secret information based on the Penuma NDA. However, even absent the
11 Penuma NDA, the circumstances of the discussion made the confidential and
12 proprietary nature of the subject matter obvious such that no reasonable person would
13 have assumed the information shared by Dr. Elist was anything but confidential and/or
14 trade secret.

15 88. Relying on the Penuma NDA, however, and assuming that Dr. Cornell
16 was genuinely interested in purchasing and using Penuma implants in his practice,
17 Dr. Elist shared with Dr. Cornell Plaintiffs' future plans to update the product design
18 of Penuma and the surgical technique associated with the placement of the Penuma
19 implant, including that future iterations of Penuma would contain internal pockets or
20 voids of space in the implant. Dr. Elist's decision to include internal pockets or voids
21 of space in future iterations of Penuma was based on his clinical observation of
22 patients' experiences with Penuma.

23 89. In this same training, Dr. Elist discussed with Dr. Cornell that he
24 intended to include one or more mesh tabs on the implant, employ absorbable sutures
25 in the surgical method, and cover Penuma in an antibacterial agent in future iterations
26 of Penuma. On information and belief, Dr. Cornell secretly took photos of Penuma's
27 non-public "Instructions for Use" during his visit. Defendants later substantially
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1 copied Penuma's "Instructions of Use" for their competing device, lifting most of the
2 terms *verbatim*.

3 90. On information and belief, prior to meeting with Dr. Elist, Dr. Cornell
4 was not aware of how Penuma was constructed at all, let alone that it could be updated
5 or modified. As someone with no experience with cosmetic penile implants, Dr.
6 Cornell certainly had no clinical observations of his own from which to draw. In
7 contrast, Dr. Elist had spent years working to develop and modify Penuma; during the
8 course of this time, Dr. Elist had developed numerous ideas and techniques to modify
9 and/or further develop Penuma. Most of these are trade secrets.

10 91. Dr. Elist's trade secrets have significant commercial value and are based
11 on his unique and vast experience with aesthetic penile implants. Not only do these
12 trade secrets allow Dr. Elist to help address the needs of more patients, but they mark
13 him as an innovator in the field of aesthetic penile implants, which itself has
14 significant innate and commercial value.

15 92. Once Dr. Cornell returned to Houston from Beverly Hills, ignoring the
16 Penuma NDA, he almost immediately began to utilize what he learned about
17 Plaintiffs' trade secrets and intellectual property to try and create a penile implant
18 using information he had learned during Penuma training and he shared much of the
19 confidential information he learned from Dr. Elist with Mische, Finger, and others for
20 that purpose. For example, on April 2, 2018, as part of Dr. Cornell's continued
21 participation in the Penuma training program, and at Dr. Cornell's request, Mr. Louie
22 sent Dr. Cornell Plaintiffs' confidential list of supplies and instruments used for the
23 Penuma implant procedure. Plaintiffs provide this confidential list to physicians only
24 after they have signed the non-disclosure agreement with IMD. A few days later, Dr.
25 Cornell sent the confidential list to Mische pursuant to their scheme to steal Plaintiffs'
26 trade secret and confidential information to develop their competing implant.

1 93. Mische was aware that Dr. Cornell was subject to the Penuma NDA
2 because Dr. Cornell sent Mische a copy of the Penuma NDA as he was also sending
3 him the Plaintiffs' confidential information in violation of that very NDA. Mische
4 even opined that the Penuma NDA did not present any issues. According to
5 Defendants' own documents, Dr. Cornell and Mische described their penile implant
6 "invention" as being described and referenced in electronic communications
7 beginning April 7, 2018, just one week after Dr. Cornell's observation of Dr. Elist's
8 Penuma implant procedures.

9 94. On April 23, 2018, Dr. Cornell contacted Mr. Louie to inquire about the
10 status of his return visit to further his Penuma training, continuing the ruse that he was
11 interested in becoming fully trained to perform the Penuma implant procedure. Yet
12 Dr. Cornell had already begun using Plaintiffs' trade secret and confidential
13 information to develop Defendants' competing Augmenta implant in violation of the
14 Penuma NDA.

15 95. On July 23, 2018, less than four months after meeting with Dr. Elist, Dr.
16 Cornell and Mische sought to capitalize on Plaintiffs' intellectual property by filing
17 their first provisional patent application for "Cosmetic Penile Implant and Related
18 Methods of Implanting," Provisional Application No. 62/702,062. This provisional
19 application was based entirely on what Dr. Cornell learned about Penuma from Dr.
20 Elist, namely that Dr. Elist was considering the inclusion of one or more mesh tabs,
21 the employment of absorbable sutures, and the use of an antibacterial agent in future
22 iterations of Penuma. Again, on December 14, 2018, Dr. Cornell and Mische filed a
23 second provisional patent application—Provisional Application No. 62/779,825,
24 "Cosmetic Penile Implant and Related Methods of Implanting."

25 96. Additionally, on or about September 21, 2018, on information and belief,
26 Dr. Cornell incorporated Augmenta LLC in the State of Delaware. On or about
27 October 15, 2018, on information and belief, Dr. Cornell registered Augmenta LLC
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1 for business within the State of Texas. On information and belief, Augmenta LLC
2 was created to utilize the intellectual property and trade secrets stolen by Dr. Cornell
3 to compete with Plaintiffs and Penuma for the benefit of Defendants.

4 97. In the latter half of 2018, Dr. Cornell and Mische ceased working
5 together and Dr. Cornell turned to Huck Medical and Nichols to continue developing
6 and commercializing Dr. Elist's intellectual property and trade secrets. On
7 information and belief, both Nichols and Huck Medical were aware that Cornell had
8 stolen trade secrets from Plaintiffs.

9 98. Furthermore, in the latter half of 2018, Dr. Wang began to provide
10 substantive advice regarding the development of Augmenta to Dr. Cornell, Dr.
11 Clavell, Huck Medical, and Nichols. On information and belief, all Defendants were
12 aware that Dr. Wang was a member of Penuma's advisory board, and as such, had
13 extensive knowledge of Penuma's trade secrets and development pipeline.

14 99. Dr. Wang was subject to a strict confidentiality clause as part the
15 Consulting Services Agreement he signed before he became a member of Penuma
16 advisory board and was trained on the Penuma implant and procedure. Nevertheless,
17 Dr. Wang provided extensive development feedback to Drs. Cornell and Clavell, as
18 well as Huck Medical and Nichols regarding the Augmenta implant, including
19 confidential information that Dr. Wang had obtained by virtue of his position as a
20 Penuma advisory board member and a surgeon who had experience with Penuma
21 implants. In exchange for his services, Dr. Wang was granted ownership interest in
22 Augmenta LLC, which he accepted through his professional limited liability
23 company, RW Global Men's Health Consultation Services. On information and
24 belief, Dr. Wang is prohibited from ownership interest in any private companies due
25 to his affiliation with The University of Texas MD Anderson Cancer Center, which
26 prohibits such private ownership.

100. Additionally, in the latter half of 2018, Defendants capitalized investment and ownership in Augmenta, LLC as follows: Augmenta, LLC owns 100 percent of the intellectual property, all of which was derived from Plaintiffs' trade secrets. Augmenta Investors LLC is a 95 percent member of Augmenta LLC and exists for the purpose of making equity investments into Augmenta LLC. The other 5 percent member of Augmenta, LLC is OAM LLC, which is 60 percent owned by Dr. Cornell and 40 percent owned by Mische. Augmenta Investors, LLC is owned by the various investors into Augmenta, LLC, with AM Founders LLC being an approximately 79 percent member and the remaining 21 percent membership being comprised of individual investors into Augmenta, LLC. On information and belief, the purpose of AM Founders LLC is to make equity investments into Augmenta Investors LLC, which in turn, is to make equity investments into Augmenta, LLC. Lata Lignum LLC, which is controlled by investor Richard Finger, is a 44 percent member of AM Founders LLC; Capital Urology Associates, which is partially owned by Drs. Cornell, Clavell, and Wang, is a 16 percent member of AM Founders LLC, and Cornell Cosmetic Urology LLC, which is owned by Dr. Cornell, is a 40 percent member of AM Founders LLC. Dr. Cornell is the voting member and/or manager for Augmenta, LLC, Augmenta Investors LLC, AM Founders LLC, Cornell Cosmetic Urology LLC, and Capital Urology Associates LLC.

101. On January 3, 2019, Dr. Cornell filed a non-provisional patent application for a silicone penile implant for cosmetic enhancement that was based entirely on the intellectual property and trade secrets Dr. Cornell had learned from Dr. Elist, including the internal pocketing, mesh tabs, absorbable sutures, and antibacterial coating. This application listed Dr. Cornell, Mische, and Nichols as co-inventors. This patent application issued as the '413 Patent on September 17, 2019. A true and correct copy of the patent prosecution history for the '413 Patent is attached as Exhibit B. Plaintiffs were not aware of this patent until after the '413 Patent issued

1 because, on information and belief, Defendants' patent application was not public or
2 was not reasonably available to Plaintiffs.

3 102. Figure 14B of the '413 Patent is an unauthorized still image from a video
4 that Dr. Elist created and placed on his YouTube channel to demonstrate the Penuma
5 implant and describe the Penuma procedure. In Dr. Elist's original video, the image
6 was accompanied by text explaining the Penuma procedure. In an attempt to
7 obfuscate the origins of the image, on information and belief, Dr. Cornell had the
8 image edited to remove the informational text from Dr. Elist's original video, which
9 also slightly truncated the image. The video from which the image was taken was
10 submitted to the United States Copyright Office for protection on or about February
11 2020, Case # 1-8530639781, and is currently pending assignment of a U.S. Copyright
12 Registration Number. A true and correct copy of the submission confirmation from
13 the United States Copyright Office is attached as Exhibit K. A true and correct copy
14 of the still image taken without authorization from Dr. Elist's Penuma video is
15 attached hereto as Exhibit L.

16 103. On March 15, 2019, the USPTO rejected all of the Defendants' claims
17 citing Dr. Elist's '204 Patent and '193 Patent as prior art. Claim 1 is the only
18 independent claim of this patent. Importantly, the USPTO rejected claim 1 and
19 several dependent claims as being anticipated by the '204 Patent. The USPTO also
20 rejected the remaining dependent claims as being obvious based on the '204 Patent in
21 combination of Dr. Elist's '193 Patent or other prior art references. In other words,
22 all claims in the Defendants' patent application for the '413 Patent were considered
23 not patentable over Dr. Elist's patent. Defendants presented nothing novel or
24 inventive in their patent application.

25 104. In order to overcome the USPTO's rejection, Dr. Cornell initiated an
26 interview with the patent examiner on April 25, 2019, where he presented Plaintiffs'
27 trade secrets as the inventive subject matter of his patent application in proposed
28

1 amendment to claim 1. Dr. Cornell fraudulently disclosed future iterations of Penuma
2 in emphasizing that the penile implant in the '413 Patent would contain internal
3 pockets or voids of space. Dr. Cornell then amended his patent claim on April 30,
4 2019, wherein he further emphasized this exact trade secret information, which Dr.
5 Cornell had learned only by visiting Dr. Elist in Beverly Hills, California, on March
6 30, 2018.

7 105. Based on this allegedly "new" information, the USPTO granted Dr.
8 Cornell the '413 Patent on September 17, 2019.

9 106. On May 22, 2019, Dr. Cornell, along with his "co-inventors," Mische
10 and Nichols, each swore under penalty of perjury that he was the "original inventor
11 or an original joint inventor of a claimed invention" in the application for the '413
12 Patent. That statement was knowingly false and punishable under 18 U.S.C. § 1001.

13 107. According to USPTO records, Dr. Cornell assigned the '413 Patent to
14 Augmenta, LLC. On information and belief, Dr. Cornell formed Augmenta, LLC to
15 market, promote, and distribute the product he created from Plaintiffs' stolen
16 intellectual property.

17 108. Contemporaneously with these actions, dating back to April 2018, Dr.
18 Cornell began falsely advertising on his website and through targeted Internet
19 advertising schemes, including utilizing Google's advertising services, that he was an
20 authorized Penuma surgeon. Dr. Clavell also falsely suggested that he performed
21 Penuma implant procedures on his website. In reality, Drs. Cornell and Clavell were
22 not authorized Penuma surgeons because they had not completed the required
23 training, nor had they been authorized to distribute Penuma implants. Consequently,
24 Drs. Cornell and Clavell had no access to Penuma implants.

25 109. The Penuma Mark is suggestive, arbitrary, or fanciful because it requires
26 a mental leap from the mark to the product. Penuma is automatically entitled to
27 trademark protection because Penuma is inherently distinct. The Penuma Mark has
28

1 been used in commerce since January 7, 2016, and continues to be used in commerce
2 by Plaintiffs.

3 110. The USPTO recognized that Penuma was entitled to be protected when
4 it issued a trademark for Penuma on September 20, 2016, U.S. Reg. No. 5044348.
5 Menova, a company wholly owned by Dr. Elist, is the sole owner of the Penuma
6 Mark. A true and correct copy of the search results for Penuma in the Trademark
7 Electronic Search System and the Penuma Registration is attached as Exhibit C.

8 111. The Penuma Mark is a valid trademark because registered marks are
9 presumed valid. Thus, the Penuma Mark is protected by United States trademark
10 laws.

11 112. On information and belief, Dr. Cornell deliberately copied the Penuma
12 Mark when he used the Penuma Mark in commerce to target interstate customers
13 interested in Penuma implants with false internet advertisements, which were
14 intended to steer business away from Dr. Elist and to Dr. Cornell's new company,
15 Augmenta. True and correct copies of Dr. Cornell's use of the Penuma Mark on Dr.
16 Cornell's website and in Google Ads are attached as Exhibits D and E, respectively.

17 113. These advertisements not only infringed on the Penuma Mark, which
18 Defendant had no authorization to use, but created confusion in the marketplace.
19 Defendants' advertisements contained misleading information about the results of the
20 Penuma implant procedure and the recovery period, advertising better results with a
21 quicker recovery time than that advertised by Penuma and Dr. Elist. As an example,
22 at the time this action was filed, Augmenta's website advertised that Augmenta's rates
23 of infection from surgery will be "significantly lower than any other type of penile
24 implant," even though, an Augmenta implant has never been actually implanted in a
25 single individual and is not cleared or approved by the FDA. On information and
26 belief, all of this was done with the aim of driving more clients to Defendants.

1 114. Potential customers were actually confused by Defendant's
2 advertisements and reached out to Dr. Elist concerning their confusion. At least 23
3 prospective patients called Dr. Elist and inquired as to whether Dr. Cornell offered
4 the Penuma implant and whether the Penuma and Augmenta implants are
5 synonymous.

6 115. On information and belief, Dr. Cornell also personally met with patients
7 wanting to receive Penuma implants and instead, attempted to redirect them to an
8 Augmenta implant despite the fact that Augmenta implants were not yet FDA-cleared
9 or approved. During these consultations, Dr. Cornell would provide negative
10 feedback regarding Penuma to patients despite never having performed a single
11 Penuma implant procedure. This was done to prevent potential patients from using
12 Penuma and to convince them to use Augmenta instead.

13 116. On information and belief, Defendants are now taking steps to
14 commercialize Augmenta utilizing Plaintiffs' stolen trade secrets and intellectual
15 property and have offered for sale both the Augmenta implant and Augmenta
16 certifications on the Augmenta website. A true and correct copy of screenshots of
17 Augmenta's website as of January 2020 are attached as Exhibit F. On or around
18 December 2019, Defendants through Augmenta, LLC submitted an application with
19 the FDA seeking clearance for the Augmenta implant. That application remains
20 pending.

21 117. Penuma is the result of years of research and development, clinical
22 studies, patent protection, trade secrets, and FDA clearance, while the Augmenta
23 implant is the result of stolen trade secrets and intellectual property, trademark
24 infringement, false and misleading advertising, copyright infringement, and no known
25 clinical tests whatsoever.

26 118. Indeed, Defendants' claims on Augmenta's website that Augmenta is
27 "designed to be the safest penile implant in the world," "allows for natural male
28

1 enhancement . . . without compromising movement or function[,] something other
2 devices can't do;" "is lighter and softer than any other cosmetic penile implant
3 available;" and is more "natural" than another "other implant in the world" are false,
4 fraudulent, misleading. Those representations are based on no actual testing of the
5 product and no FDA clearance or approval. Through those statements, Defendants
6 attempt to create a false dichotomy between Plaintiffs' intellectual property and
7 Augmenta when, in fact, Augmenta is the result of the Defendants' theft of Plaintiffs'
8 trade secrets and intellectual property. Defendants' false advertising of the Augmenta
9 implant through the Augmenta website violates FDA regulations. A true and correct
10 copy of a printout of Augmenta's website is attached as Exhibit N.

11 119. These issues loom large in the male enhancement field, which is littered
12 with nightmare anecdotes of fundamentally unsafe and harmful procedures (none of
13 which are Penuma). For this reason, Penuma's product integrity and reputation is of
14 paramount importance. Defendants' unlawful activities not only do Plaintiffs great
15 harm; those activities threaten to further damage the reputation of the penile implant
16 industry.

17 120. On information and belief, Defendants have worked in concert to further
18 harm Plaintiffs.

19 121. In October 2019, Dr. Clavell attended and observed Dr. Wang perform
20 Penuma implant procedures in Houston, Texas, on information and belief, to obtain
21 more of Plaintiffs' confidential information, including trade secrets, from Dr. Wang.
22 On information and belief, Dr. Wang provided Plaintiffs' confidential information to
23 Dr. Clavell in violation of the Consulting Services Agreement.

24 122. Dr. Clavell falsely suggested on his website that he is a properly trained
25 and authorized Penuma surgeon. On the website, as of the initiation of the filing of
26 the original complaint in this action, Dr. Clavell claims "[a ventral or cosmetic
27 phalloplasty] procedure is a simple procedure that can be made in conjunction with
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1 penile implant surgery, penis enlargement procedures, such as Penuma, or can be
2 performed on its own.” [https://houstonmenshealth.com/procedures/ventral-](https://houstonmenshealth.com/procedures/ventral-phalloplasty/)
3 [phalloplasty/](https://houstonmenshealth.com/procedures/ventral-phalloplasty/) (last visited on April 13, 2020; this website was removed after Dr.
4 Clavell was served with the original complaint, but a screenshot of the website as
5 available on March 18, 2020 is attached as Exhibit J). This statement is designed to
6 mislead visitors to Dr. Clavell’s website to think they could get a Penuma implant in
7 conjunction with a ventral or cosmetic phalloplasty procedure performed by Dr.
8 Clavell. In fact, Dr. Clavell has never had any authorization whatsoever from
9 Plaintiffs to perform the Penuma procedure. Further, Dr. Clavell does not have
10 permission to use the Penuma Mark on his website. Dr. Clavell’s actions infringe the
11 Penuma Mark and, much like the false advertising posted by Dr. Cornell, appears
12 designed to redirect prospective Penuma patients to Augmenta. Dr. Clavell has a
13 financial interest in Augmenta, LLC and the Augmenta implant. Indeed, on
14 information and belief, Dr. Clavell is listed on Augmenta’s website as a certified
15 Augment implant surgeon. Dr. Wang was at one point listed on Augmenta’s website
16 as the CEO of Augmenta, LLC. This designation was removed after IMD
17 representatives asked Dr. Wang about it.

18 123. Due to the Defendants’ actions as described herein, Plaintiffs have
19 suffered significant irreparable harm, which harm will dramatically increase absent
20 court intervention.

21 **CLAIMS FOR RELIEF**

22 **FIRST CAUSE OF ACTION**

23 **MISAPPROPRIATION OF TRADE SECRETS**

24 **(Defend Trade Secrets Act, 18 U.S.C. §§ 1836 et seq.)**

25 **(By All Plaintiffs Against All Defendants)**

26 124. Plaintiffs incorporate by reference, as though fully set forth herein, the
27 allegations of the preceding paragraphs of this Complaint.
28

1 125. Plaintiffs' ability to compete in the aesthetic and reconstructive urology
2 industry, in the United States and globally, is directly dependent on maintaining the
3 secrecy of their trade secrets and other confidential and proprietary information.

4 126. For this reason, Plaintiffs have a set of procedures in place to ensure their
5 trade secret information, including the future pocketed design of Penuma, remained
6 confidential. This information is protectable as trade secrets under the federal Defend
7 Trade Secrets Act, 18 U.S.C. §§ 1836 et seq.

8 127. Plaintiffs' trade secret information has independent economic value and
9 is not generally known or readily available to the public, including competitors.
10 Plaintiffs expended substantial time, resources, and ingenuity in developing this
11 information based on their own efforts.

12 128. Plaintiffs made reasonable efforts to ensure that all of their confidential
13 and proprietary information, including trade secrets and trade secret information,
14 remained secret by, among other things, requiring Penuma's sole contract
15 manufacturer to sign a strict confidentiality agreement, requiring a non-disclosure
16 agreement before any confidential information was disseminated to anyone else,
17 disclosing confidential information only to those individuals who needed the
18 information to perform their duties, only disclosing confidential research and
19 development information to those on Penuma's advisory board who were subject to
20 confidentiality agreements or those who had signed a non-disclosure agreement with
21 IMD and requested that information directly, and keeping track of each disclosure of
22 confidential information made and to whom.

23 129. Without the trade secret protection provided by Plaintiffs' confidentiality
24 agreements, including non-disclosure agreements, and Plaintiffs' reasonable efforts
25 to maintain the secrecy of their confidential and proprietary information, Plaintiffs
26 would be unable to distribute and expand the availability of Penuma and the Penuma
27 surgical technique beyond Dr. Elist's clinic in a manner consistent with patient safety.
28

1 130. On March 30, 2018, Dr. Cornell, Dr. Elist, and IMD entered into the
2 Penuma NDA, which forbade Dr. Cornell from disclosing or using the Confidential
3 Information. The Penuma NDA specifically defined the Confidential Information as,
4 “various information . . . which relates to past, present or future products, services,
5 software, techniques or technical information, and data, business plans, marketing
6 plans, financial statement and proformas relating to the business affairs, plans and
7 operations.” Ex. A, pg. 1. The Penuma NDA thus covered Plaintiffs’ trade secrets
8 and trade secret information, among other information.

9 131. In his meeting with Dr. Cornell, Dr. Elist disclosed the research and
10 development plans for future versions of the Penuma implant. This information was
11 not publicly known but was specifically requested by Dr. Cornell. During his visit,
12 Dr. Cornell signed the Penuma NDA. Shortly after his office visit, Dr. Cornell
13 requested and received Plaintiffs’ confidential list of surgical instruments and
14 materials for the Penuma procedure. Again, he was provided with this trade secret
15 information only because he had signed the Penuma NDA. Dr. Cornell proceeded to
16 share Plaintiffs’ confidential list with Hans Mische in breach of the Penuma NDA.
17 Dr. Cornell has also admitted under oath that Dr. Wang assisted with the design and
18 development of Augmenta – all of this occurred without Plaintiffs’ knowledge or
19 consent and while Dr. Wang served on the Penuma advisory board and in breach of
20 the Consulting Services Agreement.

21 132. Defendants violated the Defend Trade Secrets Act by misappropriating
22 Plaintiffs’ trade secret information in a willful manner and with the deliberate intent
23 to injure Plaintiffs’ business, and for Defendants’ own financial gain including,
24 without limitations and as described above, by (a) acquiring Plaintiffs’ trade secrets;
25 (b) disclosing Plaintiffs’ trade secrets to the USPTO to wrongfully obtain a patent on
26 a penile enlargement implant that was, in actuality, invented by Plaintiffs; and (c)
27 using Plaintiffs’ trade secrets for Defendants’ benefit. At all relevant time, on
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1 information and belief, Defendants knew or had reason to know that Plaintiffs' trade
2 secrets were acquired by improper and deceitful means, conspired together to obtain
3 and/or use the trade secrets, and aided and abetted each other in doing so.

4 133. As a proximate result of Defendants' misappropriation, Plaintiffs have
5 suffered and will continue to suffer actual damages, and Defendants will be unjustly
6 enriched, in sums not yet ascertained. Plaintiffs also suffered and will continue to
7 suffer immediate and irreparable harm, which will continue until Defendants'
8 misconduct is preliminarily and permanently enjoined.

9 134. Defendants' misappropriation was intentional, malicious, and in bad
10 faith, and has subjected and will continue to subject, Plaintiffs to cruel and unjust
11 hardship in conscious disregard of Plaintiffs' rights, so as to justify an award of
12 exemplary and punitive damages according to proof at trial. Further, under the
13 Defend Trade Secrets Act, Plaintiffs are entitled to recover reasonable attorneys' fees
14 as a result of Defendants' willful and malicious misappropriation.

15 **SECOND CAUSE OF ACTION**

16 **MISAPPROPRIATION OF TRADE SECRETS**

17 **(Cal. Uniform Trade Secrets Act, Cal. Civil Code §§ 3426 et seq.)**

18 **(By All Plaintiffs Against All Defendants)**

19 135. Plaintiffs incorporate by reference, as though fully set forth herein, the
20 allegations of the preceding paragraphs of this Complaint.

21 136. Plaintiffs' ability to compete in the aesthetic and reconstructive urology
22 industry in the United States and globally, is directly dependent on maintaining the
23 secrecy of their trade secrets and other confidential and proprietary information.

24 137. For this reason, Plaintiffs have a set of procedures in place to ensure their
25 trade secret information, including the future design of Penuma with internal pockets,
26 remained confidential. This information is protectable as trade secrets under the
27 California Uniform Trade Secrets Act, Cal. Civil Code §§ 3426, et seq.
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1 138. Plaintiffs' trade secret information has independent economic value and
2 is not generally known or readily available to the public, including competitors.
3 Plaintiffs expended substantial time, resources, and ingenuity in developing this
4 information based on their own efforts.

5 139. Plaintiffs made reasonable efforts to ensure that all of their confidential
6 and proprietary information, including trade secrets and trade secret information,
7 remained secret by, among other things, requiring Penuma's sole contract
8 manufacturer to sign a strict confidentiality agreement, requiring a non-disclosure
9 agreement before any confidential information was disseminated to anyone else,
10 disclosing confidential information only to those individuals who needed the
11 information to perform their duties, only disclosing confidential research and
12 development information to those on Penuma's advisory board who were subject to
13 confidentiality agreements or those who had signed a non-disclosure agreement with
14 IMD and requested that information directly, and keeping track of each disclosure of
15 confidential information made and to whom.

16 140. Without the trade secret protection provided by IMD's non-disclosure
17 agreements and Plaintiffs' reasonable efforts to maintain the secrecy of their
18 confidential and proprietary information, Plaintiffs would be unable to distribute and
19 expand the availability of Penuma and the Penuma surgical technique beyond Dr.
20 Elist's clinic in a manner consistent with patient safety.

21 141. On March 30, 2018, Dr. Cornell, Dr. Elist, and IMD entered into the
22 Penuma NDA, which forbade Dr. Cornell from disclosing or using Confidential
23 Information. The Penuma NDA specifically defines Confidential Information as,
24 "various information . . . which relates to past, present or future products, services,
25 software, techniques or technical information, and data, business plans, marketing
26 plans, financial statement and proformas relating to the business affairs, plans and
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1 operations.” Ex. A, pg. 1. The Penuma NDA thus covered Plaintiffs’ trade secrets
2 and trade secret information, among other information.

3 142. In the meeting with Dr. Cornell, Dr. Elist disclosed the research and
4 development plans for future versions of the Penuma implant. This information was
5 not publicly known and only shared with Dr. Cornell because he signed the Penuma
6 NDA, agreeing to maintain the secrecy of the Confidential Information learned in the
7 meeting and asked Dr. Elist directly about such information. Shortly thereafter, and
8 based on his request, Dr. Cornell was provided Plaintiffs’ confidential list of surgical
9 instrumental and materials used for the Penuma procedure. This information was
10 provided only because Dr. Cornell had signed the Penuma NDA. Dr. Cornell
11 proceeded to share Plaintiffs’ confidential list with Hans Mische in breach of the
12 Penuma NDA. Dr. Cornell has also admitted under oath that Dr. Wang assisted with
13 the design and development of Augmenta – all of this occurred without Plaintiffs’
14 knowledge or consent and while Dr. Wang served on the Penuma advisory board and
15 in breach of the Consulting Services Agreement.

16 143. Defendants violated the California Uniform Trade Secrets Act by
17 misappropriating Plaintiffs’ trade secret information in a willful manner and with the
18 deliberate intent to injure Plaintiffs’ business, and for Defendants’ own financial gain
19 including without limitations and as described above by (a) acquiring Plaintiffs’ trade
20 secrets; (b) disclosing Plaintiffs’ trade secrets to the USPTO to wrongfully obtain a
21 patent on a penile enlargement implant that was, in actuality, invented by Plaintiffs;
22 and (c) using Plaintiffs’ trade secrets for Defendants’ benefit. At all relevant times,
23 on information and belief, Defendants knew or had reason to know that Plaintiffs’
24 trade secrets were acquired by improper and deceitful means, conspired together to
25 obtain and/or use the trade secrets, and aided and abetted each other in doing so.

26 144. As a proximate result of Defendants’ misappropriation, Plaintiffs have
27 suffered and will continue to suffer actual damages, and Defendants will be unjustly
28

1 enriched, in sums not yet ascertained. Plaintiffs also suffered and will continue to
2 suffer immediate and irreparable harm, which will continue until Defendants'
3 misconduct is preliminarily and permanently enjoined.

4 145. Defendants' misappropriation was intentional, malicious, and in bad
5 faith, and has subjected and will continue to subject, Plaintiffs to cruel and unjust
6 hardship in conscious disregard of Plaintiffs' rights, so as to justify an award of
7 exemplary and punitive damages according to proof at trial. Further, under the
8 California Uniform Trade Secrets Act, Plaintiffs are entitled to recover reasonable
9 attorneys' fees as a result of Defendants' willful and malicious misappropriation.

10 **THIRD CAUSE OF ACTION**

11 **RICO (18 U.S.C. § 1962(c))**

12 **(By All Plaintiffs Against All Defendants)**

13 146. Plaintiffs incorporate by reference, as though fully set forth herein, the
14 allegations of the preceding paragraphs of this Complaint.

15 147. Defendants' violation of the Defend Trade Secrets Act constitutes a
16 pattern of racketeering activity pursuant to 18 U.S.C. § 1961.

17 148. Defendants are all persons within the meaning of 18 U.S.C. § 1961(3).

18 149. Defendants perpetrated a scheme whereby they misappropriated
19 Plaintiffs' trade secrets, confidential information, and intellectual property in
20 violation of the Defend Trade Secrets Act, as further set forth above in this Complaint.

21 150. Defendants purposefully directed their conduct at Plaintiffs in California.
22 Defendants intentionally targeted California and have continued to misappropriate
23 Plaintiffs' trade secrets.

24 151. Defendants' formed their scheme for the express purpose of unlawfully
25 utilizing Plaintiffs' trade secrets, confidential information, and intellectual property
26 misappropriated by Defendants from Plaintiffs in California.

1 152. Defendants and their association-in-fact constitute an enterprise, and
2 they engaged in and acted in concert with each other to misappropriate Plaintiffs’
3 trade secrets, confidential information, and other property. The enterprise is engaged
4 in and its activities affect interstate commerce.

5 153. Defendants, by and through their improper and fraudulent activities and
6 wrongful conduct, willfully and with actual knowledge, agreed to and did conduct
7 and participate in the conduct of the enterprise affairs through a pattern of racketeering
8 activity for the purposes of intentionally misappropriating Plaintiffs’ trade secrets,
9 confidential information, and intellectual property used in Plaintiffs’ business in
10 California.

11 154. In furtherance of their illegal schemes in violation of the Defend Trade
12 Secrets Act, Defendants willfully and with actual knowledge committed multiple acts
13 over a long span of time between 2018 to the present, including, but not limited to,
14 the unlawful theft and continuing misappropriation of Plaintiffs’ trade secrets,
15 confidential information, and intellectual property from Plaintiffs in California
16 through interstate or foreign commerce.

17 155. Defendants both directly and indirectly participated in the conduct of the
18 enterprises’ affairs through the pattern racketeering of activity described herein, in
19 violation of 18 U.S.C. §§ 1962(c) and 1964(c).

20 156. As a direct and proximate result of Defendants’ racketeering activities,
21 Plaintiffs have been injured in California in their business and property, including loss
22 and misappropriation of trade secrets, confidential information and intellectual
23 property that have been used or are continuing to be used to further the interests of
24 Defendants in derogation of Plaintiffs’ rights.

25 157. As a result of Defendants’ racketeering activities and enterprise,
26 Plaintiffs’ business in California has been damaged, and it continues to be damaged,
27 in an amount to be proven at trial.

FOURTH CAUSE OF ACTION

RICO (18 U.S.C. § 1962(d))

(By All Plaintiffs Against All Defendants)

158. Plaintiffs incorporate by reference, as though fully set forth herein, the allegations of the preceding paragraphs of this Complaint.

159. Defendants have intentionally conspired and agree to directly and indirectly participate in the affairs of the Enterprise through a pattern of racketeering activities in violation of 18 U.S.C. § 1832, as more fully described in the Third Cause of Action.

160. Defendants knew that their actions constituted a pattern of racketeering activities and agreed to those actions in furtherance of, and for the benefit of the enterprise, as described in the Third Cause of Action.

161. The actions of Defendants constitute a conspiracy to violate 18 U.S.C. § 1962(c) in violation of 18 U.S.C. § 1962(d).

162. As a direct and proximate result of racketeering activities and violations of 18 U.S.C. § 1962(d) by the Defendants, Plaintiffs have suffered damages in an amount to be proven at trial.

163. The aforementioned acts of the Defendants were done willfully, with malice toward Plaintiffs, entitled Plaintiffs to treble damages, attorneys' fees, and costs.

FIFTH CAUSE OF ACTION

TRADEMARK INFRINGEMENT

(15 U.S.C. §§ 1114, 1125(a))

**(By All Plaintiffs Against Dr. Cornell, the Cornell PA, Dr.
Clavell, and the Clavell PA)**

164. Plaintiffs incorporate by reference, as though fully set forth herein, the allegations of the preceding paragraphs of this Complaint.

1 165. On January 10, 2016, Menova filed for the Penuma Mark. The USPTO
2 federally registered the Penuma Mark on September 20, 2016 (U.S. Reg. No.
3 5044348), which is owned by Menova. A true and correct copy of the search results
4 for Penuma in the Trademark Electronic Search System and the registration certificate
5 are attached as Exhibit C.

6 166. The Penuma Mark has been used in commerce since January 7, 2016.
7 Plaintiffs continue to use the mark on Dr. Elist's website, Penuma's website
8 (<http://penuma.com>), and on informational and marketing material. The Penuma
9 Mark is suggestive, arbitrary, or fanciful because it requires a mental leap from the
10 mark to the product. The Penuma Mark is automatically entitled to trademark
11 protection because the mark is inherently distinct.

12 167. During the March 30, 2018 meeting between Dr. Cornell and Dr. Elist,
13 none of the Plaintiffs guaranteed any future collaboration with Dr. Cornell or that they
14 would sell Penuma to Dr. Cornell. Further, Menova and Dr. Elist never authorized
15 Dr. Cornell to use the Penuma Mark.

16 168. Nevertheless, Dr. Cornell and the Cornell PA developed a dedicated
17 section of their medical practice's website to Penuma and began to advertise Dr.
18 Cornell as a Penuma surgeon on targeted Internet advertising campaigns, such as
19 those run by Google. True and correct copies of Dr. Cornell's website and the Google
20 ads are attached as Exhibits D and E.

21 169. Dr. Cornell's website on Penuma is likely to cause consumer confusion
22 or to deceive consumers who believe they can obtain a Penuma implant from Dr.
23 Cornell's clinic even though Dr. Cornell does not perform the Penuma procedure.
24 Plaintiffs, the exclusive source of Penuma, have never sold the implant to Dr. Cornell
25 or authorized Dr. Cornell to offer Penuma for sale.

1 170. On June 25, 2018, IMD sent Dr. Cornell a cease and desist email,
2 demanding that Dr. Cornell refrain from further use of the Penuma Mark. A true and
3 correct copy of the email is attached as Exhibit G.

4 171. Despite demanding that Dr. Cornell cease use of the Penuma Mark, Dr.
5 Cornell and the Cornell PA continued to use the Penuma Mark on their website for
6 over a year. During this period, Dr. Cornell and the Cornell PA made numerous false
7 representations about the product, including falsely detailing the type of anesthesia
8 used, incorrectly stating the length of time patients must abstain from sexual activity,
9 overpromising the results of such procedure, and falsely advertising the availability
10 of the Penuma implant at their Houston clinic.

11 172. On August 4, 2019, IMD emailed Dr. Cornell and stated that IMD
12 received confusing inquiries from potential patients who believed Penuma was
13 already available at Dr. Cornell and the Cornell PA's clinic in Houston due to a page
14 on their website. IMD noted that the webpage was extremely problematic and was
15 damaging to Plaintiffs because of its inaccuracies. IMD requested Dr. Cornell fix the
16 inaccuracies about Penuma or take down the web page. On August 5, 2019, Dr.
17 Cornell assured IMD that all mentions of Penuma would be removed from the
18 website. True and correct copies of the August 4, 2019 email and August 5, 2019
19 email are attached as Exhibit H.

20 173. Despite these assertions, Dr. Cornell and the Cornell PA continued to use
21 the Penuma Mark on their website. Dr. Cornell and the Cornell PA claim "[v]entral
22 phalloplasty genital contouring is a technically simple procedure that Dr. Cornell
23 often performs in conjunction with Penuma penile enhancement surgery to increase
24 penile length or girth." This statement infringes on the Penuma Mark and is also false
25 and inaccurate as Dr. Cornell has never performed the Penuma penile enhancement
26 surgery. A true and correct copy of the webpage as it existed in January 2020 is
27 attached as Exhibit I.
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1 174. Dr. Cornell and the Cornell PA also blatantly ignored Plaintiffs' cease
2 and desist emails when they paid for Google Ads using the Penuma Mark. A true and
3 correct copy of an ad for Penuma by Dr. Cornell and/or the Cornell PA is attached as
4 Exhibit E.

5 175. On information and belief, the Google ads were live starting as early as
6 mid-April 2018, and remained live even after this action was initiated in April 2020.

7 176. In addition, Dr. Clavell and the Clavell PA deliberately mislead visitors
8 to their website that defendant Dr. Clavell is a properly trained and authorized Penuma
9 surgeon. Dr. Clavell and the Clavell PA advertise on the website that "[a ventral or
10 cosmetic phalloplasty] procedure is a simple procedure that can be made in
11 conjunction with penile implant surgery, penis enlargement procedures, such as
12 Penuma, or can be performed on its own." This statement is misleading and designed
13 to convince visitors to their website to think they could get a Penuma implant in
14 conjunction with a ventral or cosmetic phalloplasty procedure performed by Dr.
15 Clavell. Dr. Clavell and the Clavell PA do not have permission to use the Penuma
16 Mark on their website, and they are not authorized to perform Penuma implants.
17 Among other things, the Dr. Clavell's and the Clavell PA's use of the Penuma Mark
18 on their website constitutes trademark infringement. A true and correct copy of the
19 webpage as it existed in March 2020 is attached as Exhibit J.

20 177. Plaintiffs have been, and absent injunctive relief will continue to be,
21 irreparably harmed by Defendants' actions. Plaintiffs are entitled to a preliminary
22 and permanent injunction pursuant to 15 U.S.C. § 1116 restraining and enjoining
23 Defendants and their agents and employees, and all persons acting on their behalf,
24 from using the Penuma Mark in commerce.

25 178. The infringement by Dr. Cornell, the Cornell PA, Dr. Clavell, and the
26 Clavell PA was intentional, malicious, and in bad faith and has subjected and will
27 continue to subject Plaintiffs to cruel and unjust hardship in conscious disregard of
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1 Plaintiffs' rights, so as to justify an award of exemplary and punitive damages
2 according to proof at trial.

3 179. Further, this constitutes an exceptional case within the meaning of
4 Section 35 of the Lanham Act, 15 U.S.C. § 1117, for which Plaintiffs are entitled to
5 recover their attorneys' fees.

6 **SIXTH CAUSE OF ACTION**

7 **COUNTERFEIT MARK**

8 **(15 U.S.C. § 1117)**

9 **(By All Plaintiffs Against the Dr. Cornell, the Cornell PA, Dr.**

10 **Clavell, and the Clavell PA)**

11 180. Plaintiffs incorporate by reference, as though fully set forth herein, the
12 allegations of the preceding paragraphs of this Complaint.

13 181. The Penuma Mark was registered for implants comprising of natural,
14 non-living material with the USPTO on September 20, 2016.

15 182. Dr. Cornell and the Cornell PA intentionally used the Penuma Mark,
16 knowing that it was a counterfeit mark, in connection with offering to sale a penile
17 implant when they purchased Google Ads and when they advertised the product on
18 Dr. Cornell and the Cornell PA's website. True and correct copies of the website and
19 Google Ads are attached as Exhibits D and E.

20 183. Dr. Clavell and the Clavell PA intentionally used the Penuma Mark,
21 knowing that it was a counterfeit mark, in connection with offering cosmetic
22 phalloplasty procedures on their website.

23 184. Because the Defendants used the Penuma name, the mark they used in
24 their advertisements was identical to the genuine Penuma Mark held by Menova.

25 185. By utilizing the Penuma Mark to direct consumer traffic to Defendants'
26 website and then offer them an implant comprising of natural, non-living material to
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1 consumers that is not the Penuma implant, but is instead the Augmenta implant,
2 Defendants violated [15 U.S.C. § 1117](#).

3 186. Because Defendants have utilized a counterfeit mark, Plaintiffs are
4 entitled to treble the actual amount of damages, or statutory damages, at their election.

5 **SEVENTH CAUSE OF ACTION**

6 **COPYRIGHT INFRINGEMENT**

7 **(17 U.S.C. § 501)**

8 **(By All Plaintiffs Against Dr. Cornell, Mische, and Nichols)**

9 187. Plaintiffs incorporate by reference, as though fully set forth herein, the
10 allegations of the preceding paragraphs of this Complaint.

11 188. On or about October 2014, Plaintiffs created a video entitled “Penile
12 Enlargement Implant Surgery Animation Video” (the “Video”) and posted it on
13 YouTube. The Video is protected copyright.

14 189. On or about February 2020, Plaintiffs sent a completed application form,
15 the requisite filing fee, and a copy of the Video to the United States Copyright Office,
16 Case # 1-8530639781. The Video is currently pending assignment of a U.S.
17 Copyright Registration Number.

18 190. On information and belief, on or about July 2018, Defendants captured
19 a still image from the Video, truncated it to obfuscate its origins, and used it without
20 authorization as an image in Defendants’ patent applications for the Augmenta
21 implant.

22 191. Defendants’ actions constitute copyright infringement. As a direct and
23 proximate result thereof, Plaintiffs are entitled to recover from Defendants actual
24 damages as a result of the infringement, as well as any of Defendants’ profits
25 attributable to the infringement in an amount according to proof at trial.

26 192. Plaintiffs further are entitled to recover their attorneys’ fees and full costs
27 pursuant to [17 U.S.C. § 505](#).

1 193. Defendants' copyright infringement was intentional, malicious, and in
2 bad faith, and has subjected, and will continue to subject, Plaintiffs to cruel and unjust
3 hardship in conscious disregard of Plaintiffs' rights, so as to justify an award of
4 exemplary and punitive damages according to proof at trial.

5 **EIGHTH CAUSE OF ACTION**

6 **BREACH OF CONTRACT**

7 **(By IMD Against Dr. Cornell and Dr. Wang)**

8 194. Plaintiffs incorporate by reference, as though fully set forth herein, the
9 allegations of the preceding paragraphs of this Complaint.

10 195. On March 30, 2018, Dr. Cornell, Dr. Elist, and IMD entered the Penuma
11 NDA, wherein Dr. Cornell agreed to "protect and hold in the strictest confidence the
12 Confidential Information; [] not disclose any Confidential Information to any person
13 or entity, unless required by law or other regulatory authority . . . and [] not use
14 directly or indirectly the Confidential Information for its own benefit or benefit of any
15 other person." The definition of "Confidential Information" included, among other
16 things, information relating to "past, present, or future products, services, []
17 techniques or technical information and data" regarding Penuma. The definition of
18 Confidential Information thus included, but was not limited to, trade secrets and trade
19 secret information.

20 196. Dr. Cornell had access to Confidential Information from Plaintiffs,
21 including, but not limited to, trade secrets and/or trade secret information. Dr. Cornell
22 then exploited this Confidential Information when he claimed to develop Augmenta
23 and filed for a patent on the product without Plaintiffs' consent.

24 197. Dr. Cornell breached the Penuma NDA when he used Confidential
25 Information, including, but not limited to, trade secrets and/or trade secret
26 information, to create, develop, and seek patents for the Augmenta implant.
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1 198. Dr. Cornell's breach of the Penuma NDA and use of Confidential
2 Information, including, but not limited to, trade secrets and/or trade secret
3 information, has caused, and will continue to cause, damage to the Plaintiffs in an
4 amount to be proven at trial.

5 **NINTH CAUSE OF ACTION**

6 **BREACH OF CONTRACT**

7 **(By IMD Against Dr. Wang)**

8 199. On October 25, 2017, IMD and Dr. Wang entered the Consulting
9 Service Agreement, wherein Dr. Wang agreed to participate as a member of
10 Penuma's advisory board in order to provide assistance in developing strategies and
11 tactics that may be used to educate providers about Penuma and address challenges
12 they may encounter. Section 4.1 of the Consulting Services Agreement included a
13 strict confidentiality term that prohibited Dr. Wang from disclosing "Confidential
14 Information", defined as "any information [Dr. Wang] acquires from [IMD],
15 including the terms of the Agreement, and any material, information, data, and
16 devices developed in the course of performing the Consulting Services." Ex. M, §
17 4.1. Dr. Wang was also required to return any confidential information he had
18 received upon expiration of the Consulting Services Agreement. Ex. M, § 4.2.

19 200. Dr. Wang also agreed to "assign to [IMD] any ideas, inventions,
20 improvements, or suggestions ("Inventions") arising from [Dr. Wang's]
21 performance of the Consulting Services, whether made alone or in conjunction with
22 others. [Dr. Wang] shall disclose such Inventions fully to Company and help
23 Company file for patents or seek other protection . . ." Ex. M, § 5.1.

24 201. Upon entering the Consulting Services Agreement, Dr. Wang
25 understood he would be "given access to substantial and significant confidential
26 information and trade secrets in order to allow him to perform his consulting
27 services." Ex. M, § 7.3. Dr. Wang expressly agreed that IMD "would suffer
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1 immediate and irreparable harm is such Confidential Information and trade secrets
2 were disclosed to or use for the benefit of any of [IMD's] competitors.” Ex. M, §
3 7.3.

4 202. Pursuant to the Consulting Services Agreement and his position on
5 Penuma's advisory board, Dr. Wang was given extensive access to Plaintiffs'
6 confidential information, trade secrets and plans for future development of Penuma.
7 Dr. Wang exploited his position on the Penuma advisory board and his access to
8 Plaintiffs' confidential and trade secret information to assist his co-defendants in
9 developing the competitor Augmenta implant and gain a financial interest in its
10 distribution. On information and belief, Dr. Wang also helped facilitate distribution
11 deals for Augmenta in China.

12 203. Dr. Wang breached section 4.1 of the Consulting Services Agreement
13 when he used Confidential Information, including, but not limited to, trade secrets
14 and/or trade secret information, to provide substantial assistance to the development
15 of the competitor Augmenta implant in coordination with his co-defendants. Dr.
16 Wang's breach of section 4.1 is further evidenced by his failure to return any
17 Confidential Information he received from IMD upon expiration of the Consulting
18 Services Agreement, another requirement of the contract.

19 204. Dr. Wang also breached section 5.1 of the Consulting Services
20 Agreement by failing to assign to IMD his equity stake in Augmenta LLC, which is
21 a product of Dr. Wang's use of the Confidential Information he acquired from IMD.

22 205. Dr. Wang remained a member of Penuma's advisory board until
23 August 2020.

24 206. Dr. Wang's breach of the Consulting Services Agreement and use of
25 Confidential Information, including, but not limited to, trade secrets and/or trade
26 secret information, has caused, and will continue to cause, irreparable harm and
27 damage to the Plaintiffs in an amount to be proven at trial.
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TENTH CAUSE OF ACTION

BREACH OF COVENANT OF GOOD FAITH AND FAIR DEALING

(By IMD Against Dr. Cornell and Dr. Wang)

207. Plaintiffs incorporate by reference, as though fully set forth herein, the allegations of the preceding paragraphs of this Complaint.

208. IMD, Dr. Elist, and Dr. Cornell entered into the Penuma NDA, an agreement with an effective date of March 30, 2018. IMD and Dr. Wang entered into the Consulting Services Agreement, an agreement with an effective date of October 25, 2017, which was amended and renewed on June 8, 2018.

209. The implied covenant of good faith and fair dealing is implied into all contracts under California law. That covenant obligated Dr. Cornell to perform the terms and conditions of the Penuma NDA fairly and in good faith, and to refrain from doing any act that would deprive IMD of the benefits of the contract. Likewise, it obligated Dr. Wang to perform the terms and conditions of the Consulting Services Agreement fairly and in good faith, and to refrain from doing any action that would deprive IMD of the benefits of the contract.

210. Dr. Cornell and Dr. Wang breached the covenant of good faith and fair dealing implied into the Penuma NDA and Consulting Services Agreement, respectively, by using Plaintiffs' Confidential Information, including, but not limited to, trade secrets and/or confidential information to design and develop Augmenta.

211. Dr. Cornell's and Dr. Wang's breaches of the implied covenant of good faith and fair dealing and use of Plaintiffs' Confidential Information has caused, and will continue to cause, damage to IMD.

ELEVENTH CAUSE OF ACTION

UNFAIR COMPETITION

(Cal. Bus. & Prof. Code § 17200)

(By All Plaintiffs Against All Defendants)

1 the issuance of the '413 Patent. Accordingly, the '413 Patent should be declared
2 unenforceable and/or invalid in its entirety.

3 218. Because the '413 Patent was granted solely on the basis of Plaintiffs'
4 intellectual property, trade secrets, and trade secret information, the Court should
5 declare that the true and sole inventor, and the only assignee, of Patent No. US
6 10,413,413 B1 is Dr. Elist.

7 219. Alternatively, because the '413 Patent contains no new novel invention
8 by the named inventors, excludes any true inventor, and is solely derivative of Dr.
9 Elist's intellectual property, trade secrets, and trade secret information, the Court
10 should declare the '413 Patent is unenforceable and/or invalid in its entirety.

11 220. Defendants' pending '821 Application is a purported invention
12 comprising of Dr. Elist's trade secrets and intellectual property. The named inventors,
13 Dr. Cornell, Hans Mische, and David Nichols, did not conceive nor reduced to
14 practice the subject matter of the '821 Application. Accordingly, as with the '413
15 Patent, the Court should declare that Dr. Elist is the true and sole inventor of the '821
16 Application.

17 221. Alternatively, the Court should declare the '821 Application voided.

18 **THIRTEENTH CAUSE OF ACTION**

19 **FALSE ADVERTISING**

20 **(15 U.S.C. § 1125(a))**

21 **(By All Plaintiffs Against Dr. Cornell and Augmenta, LLC)**

22 222. Plaintiffs incorporate by reference, as though fully set forth herein, all
23 allegations of the proceeding paragraphs of this Complaint.

24 223. This Court has jurisdiction over this Thirteenth Cause of Action based
25 on federal question jurisdiction.

1 224. Defendants Dr. Cornell and Augmenta, LLC promote, advertise,
2 market, and list for sale the Augmenta implant throughout California and the United
3 States on the internet.

4 225. Dr. Cornell and Augmenta, LLC's website includes false and
5 misleading promotional content regarding the Augmenta implant, including that the
6 Augmenta implant is "safe and effective" despite not having FDA clearance. Such
7 promotion of a medical device is prohibited by FDA regulations until the FDA has
8 approved the device for commercial distribution. 21 C.F.R. § 812.7(b). On
9 information and belief, Defendants have no evidence that the Augmenta implant is
10 safe and effective once implanted in actual patients. Dr. Cornell and Augmenta,
11 LLC also made available on their website an informed consent form that stated,
12 "[i]n December 2019, the Augmenta subcutaneous silicone penile implant was
13 approved by the United States Food and Drug Administration (FDA) for use in
14 penile augmentation and reconstruction." This statement is false. The promotions
15 also impliedly and falsely disparage the Penuma as too rigid and unnatural. Such
16 misrepresentations were and are likely to influence customers' and potential
17 customers' purchasing decisions.

18 226. On information and belief, the action of defendants Dr. Cornell and
19 Aumenta, LLC have deceived and are likely to deceive a significant portion of the
20 consuming public for cosmetic penile implants, including Plaintiffs' and
21 Defendants' existing and potential customers, about the nature and qualities of
22 Defendants' Augmenta implant. Plaintiffs have received calls and messages from
23 potential customers confused about the Augmenta implant in relation to the Penuma.

24 227. On information and belief, the actions of defendants Dr. Cornell and
25 Augmenta, LLC have caused consumers to not purchase the Penuma from Plaintiffs
26 who otherwise would have done so. On information and belief, Dr. Cornell and
27 Augmenta, LLC's actions have diverted customers from Plaintiffs to Defendants.
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228. As an actual and proximate result of defendants Dr. Cornell and Augmenta, LLC's acts of false, deceptive, and misleading descriptions of fact, representations, and advertising, Plaintiffs have suffered and will continue to suffer irreparable injury to their business, reputation and goodwill. Plaintiffs have no adequate remedy at law for these wrongs and injuries. The damage to Plaintiffs includes harm to goodwill and reputation that money cannot compensate. Plaintiffs are, therefore, entitled to a preliminary and permanent injunction, as set forth in 15 U.S.C. § 1117, restraining and enjoining Defendants and their agents, servants, and employees, and all persons acting thereunder, in concert with, or on their behalf, from engaging in false advertising and from otherwise making or utilizing false and misleading statements in connection with the promotion, advertisement or sale of the Augmenta implant.

229. Plaintiffs seek compensatory damages in the amount which will compensate for all detriment caused by defendants Dr. Cornell and Augmenta, LLC.

230. As an actual and proximate result of the actions of defendants Dr. Cornell and Augmenta, LLC, Plaintiffs have suffered damages in the form of lost profits. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations, an accounting of profits made Defendants, and restitution and disgorgement of Defendants ill-gotten gains, as well as recovery of costs of this action.

231. Plaintiffs are informed and believe that Dr. Cornell's and Augmenta, LLC's conduct was undertaken willfully and with the intention of causing confusion, mistake, or deception, making this an exception case entitling Plaintiffs to recover additional damages and reasonable attorney's fees pursuant to 15 U.S.C. § 1117.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- 1 1. For an injunction restraining and enjoining the Defendants, their agents,
2 employees, and all other persons acting in concert or participating with them:
 - 3 a. From disclosing or using any proprietary, confidential, or trade
4 secret information obtained from Plaintiffs;
 - 5 b. From using in commerce the Penuma Mark;
 - 6 c. From commercializing in any way Augmenta, including, but not
7 limited to, offering Augmenta for sale;
 - 8 d. From representing by any means whatsoever that Augmenta is
9 associated with Plaintiffs, and from otherwise acting in a way
10 likely to cause confusion, mistake, or deception on the part of
11 consumers as to the origin or sponsorship of such products;
 - 12 e. From doing any other acts or things calculated or likely to cause
13 confusion or mistake in the minds of the consuming public or to
14 lead consumers to believe that Augmenta comes from Plaintiffs or
15 is somehow sponsored or licensed by, or associated with or
16 affiliated with, Plaintiffs or Penuma;
 - 17 f. From making any false or misleading statements in connection
18 with Augmenta, including, but not limited to, any false claims of
19 superiority to Penuma;
 - 20 g. From otherwise unfairly competing with Plaintiffs;
 - 21 h. To return all proprietary, confidential, and trade secret
22 information and other property misappropriated or otherwise
23 obtained from Plaintiffs;
 - 24 i. From commercializing, or in any other manner, marketing,
25 developing, promoting, and/or profiting from Plaintiffs'
26 proprietary, confidential, and trade secret information, including
27 the '413 Patent and the '821 Application, including through the
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1 withdrawal of any pending regulatory submissions with the FDA
2 and any other regulatory bodies; and

3 j. From pursuing any domestic or international patent applications
4 that involve Plaintiffs' proprietary, confidential, or trade secret
5 information, and to withdraw any such applications currently in
6 process, including the '821 Application;

7 2. For a declaration that Dr. Elist is the true and sole inventor, and the only
8 assignee, of the '413 Patent and '821 Application or, alternatively, that the '413 Patent
9 and the '821 Application are invalid;

10 3. For compensatory and consequential damages permitted by law
11 according to proof;

12 4. For restitution for unjust enrichment according to proof;

13 5. For punitive and exemplary damages according to proof;

14 6. For statutory damages where authorized and according to proof;

15 7. For prejudgment interest at the maximum legal rate;

16 8. For costs of suit;

17 9. For attorneys' fees as provided by statute or agreement; and

18 10. For such other and further relief as the Court deems just and proper.
19

20 Dated: October 1, 2020

BAKER MARQUART LLP

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24 By: /s/ Ryan G. Baker

Ryan G. Baker

Attorneys for Plaintiffs,

INTERNATIONAL MEDICAL DEVICES,

MENOVA, and DR. ELIST
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